| **Author, year** | **Group1** | **Group2** | **Outcome (definition)** | **Adverse event collection / ITT** | **Results, Group 1** | **Results, Group 2** |
| --- | --- | --- | --- | --- | --- | --- |
| Mantzaris, 200988 | Hydrocortisone + infliximabRoute: IVDose: 250 mg every 8 wks + 5 mg/kg every 8 wks | Azathioprine + infliximabRoute: Oral + IVDose: 2.0-2.5 mg/kg every 1 d + 5 mg/kg every 8 wks | CDAI (Remission: CDAI < 150) @ 104 wks | NAYes | Incidence 18 / 23 (78%) | Incidence 17 / 23 (74%) P: 1 |
| Mantzaris, 2009102 | AzathioprineRoute: OralDose: 2.0-2.5 mg/kg every 1 d | BudesonideRoute: OralDose: 6-9 mg every 1 d | CDAI (Relapse rate definition: CDAI increase >100 and >150 total) @ 52 wks | NAYes | Incidence 8 / 38 (21%) | Incidence 14 / 39 (36%) P: 0.2 |
| Mantzaris, 2009102 | AzathioprineRoute: OralDose: 2.0-2.5 mg/kg every 1 d | BudesonideRoute: OralDose: 6-9 mg every 1 d | CDAI (Relapse rate definition: CDAI increase >100 and >150 total) @ 78 wks | NAYes | Incidence 9 / 38 (24%) | Incidence 25 / 39 (64%) P: 0.03 |
| Mantzaris, 2009102 | AzathioprineRoute: OralDose: 2.0-2.5 mg/kg every 1 d | BudesonideRoute: OralDose: 6-9 mg every 1 d | Endoscopic healing (CDEIS) @ 52 wks | NAYes | B: Mean, 7.2 (SD, 3.1)F: Mean, 1.62 (SD, 2.58) P: <0.0001F-B: Mean, -5.58 P: <0.001G1-G2: 5.7 | B: Mean, 7.1 (SD, 3.5)F: Mean, 7.2 (SD, 3.2) P: <0.0001F-B: Mean, 0.1 P: 1 |
| Mantzaris, 2009102 | AzathioprineRoute: OralDose: 2.0-2.5 mg/kg every 1 d | BudesonideRoute: OralDose: 6-9 mg every 1 d | Endoscopic healing (complete or near complete mucosal healing') @ 52 wks | NAYes | Incidence 32 / 38 (83%) | Incidence 9 / 39 (24%) P: 0.0001 |
| Mantzaris, 2009102 | AzathioprineRoute: OralDose: 2.0-2.5 mg/kg every 1 d | BudesonideRoute: OralDose: 6-9 mg every 1 d | AHS-average histology score @ 52 wks | NAYes | B: Mean, 5.92 (SD, 1.7)F: Mean, 2.92 (SD, 1.93) P: <0.01F-B: Mean, -3 (SD, 0.23) P: <0.01G1-G2: 3.3 | B: Mean, 5.72 (SD, 1.63)F: Mean, 6.01 (SD, 1.72) P: <0.01F-B: Mean, 0.29 (SD, 0.09) P: 0.31 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Need for surgery (CD-related surgeries except for drainage of abscess and placement of a seton - responders) @ 52 wks | NANo | Incidence 1 / 172 (0.6%) | Incidence 7 / 170 (4.1%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (all-cause hospitalizations - responders) @ 52 wks | NANo | Incidence 25 / 172 (14.3%)RH: 0.47 (0.25 to 0.89) vs. main | Incidence 42 / 170 (24.8%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations - responders) @ 52 wks | NANo | Incidence 17 / 172 (9.7%)RH: 0.55 (0.25 to 1.22) vs. main | Incidence 23 / 170 (13.4%) P: 0.12 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Need for surgery (CD-related surgeries except for drainage of abscess and placement of a seton - responders) @ 52 wks | NANo | Incidence 0 / 157 (0%) | Incidence 7 / 170 (4.1%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations - responders) @ 52 wks | NANo | Incidence 4 / 157 (2.8%)RH: 0.15 (0.04 to 0.51) vs. main | Incidence 23 / 170 (13.4%) P: <0.01 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (all-cause hospitalizations - responders) @ 52 wks | NANo | Incidence 9 / 157 (5.6%)RH: 0.16 (0.06 to 0.39) vs. main | Incidence 42 / 170 (24.8%) P: <0.02 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Need for surgery (major CD-related surgeries, excluding drainage of abscess and placement of a seton) @ 52 wks | NAYes | Incidence 1 / 260 (0.4%) | Incidence 10 / 261 (3.8%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations) @ 52 wks | NAYes | Incidence 16 / 260 (6%) | Incidence 26 / 261 (10%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (all-cause hospitalizations) @ 8 wks | NAYes | Incidence 14 / 260 (5.2%) | Incidence 34 / 261 (13.1%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations) @ 8 wks | NA NA | Incidence 7 / 260 (2.8%) | Incidence 23 / 261 (9%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations) @ 52 wks | NAYes | Incidence 21 / 260 (8%)RH: 0.5 (0.26 to 0.94)P: 0.03 vs. main | Incidence 40 / 261 (15.5%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (all-cause hospitalizations) @ 52 wks | NAYes | Incidence 32 / 260 (12.2%)Hazard ratio: 0.45 (0.27 to 0.75)P: 0.003 vs. main | Incidence 66 / 261 (25.2%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Need for surgery (major CD-related surgeries, excluding drainage of abscess and placement of a seton) @ 52 wks | NAYes | Incidence 2 / 257 (0.8%) | Incidence 10 / 261 (3.8%) P: <0.05 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (all-cause hospitalizations) @ 8 wks | NAYes | Incidence 13 / 257 (4.9%) | Incidence 34 / 261 (13.1%) P: <0.01 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations) @ 8 wks | NA NA | Incidence 9 / 257 (3.4%) | Incidence 23 / 261 (9%) P: <0.02 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations) @ 52 wks | NAYes | Incidence 14 / 257 (5.6%)RH: 0.34 (0.17 to 0.68)P: 0.002 vs. main | Incidence 40 / 261 (15.5%) |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (all-cause hospitalizations) @ 52 wks | NAYes | Incidence 26 / 257 (10%)Hazard ratio: 0.36 (0.21 to 0.62) vs. main | Incidence 66 / 261 (25.2%) P: <0.01 |
| Feagan, 200890 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Number of hospitalizations (CD-related hospitalizations) @ 52 wks | NAYes | Incidence 13 / 257 (5%) | Incidence 26 / 261 (10%) |
| Van Assche, 200889 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | Infliximab + immunomodulatorRoute: IV + OralDose: 5 mg/kg every 8 wks  | CDAI (Absolute CDAI) @ 104 wks | NAYes | F: Median, 104 (IQR, 55 to 165) | F: Median, 92 (IQR, 34 to 164) |
| Van Assche, 200889 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | Infliximab + immunomodulatorRoute: IV + OralDose: 5 mg/kg every 8 wks  | Endoscopic healing (SES-CD) @ 104 wks | NA NA | F: Median, 2.5 | F: Median, 1 |
| Van Assche, 200889 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | Infliximab + immunomodulatorRoute: IV + OralDose: 5 mg/kg every 8 wks  | Endoscopic healing (Absence of ulcers) @ 104 wks | NANR | Incidence 14 / 23 (61%) | Incidence 16 / 25 (64%) |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Remission) @ 4 wks | NANo | Incidence 30 / 130 (23%) | Incidence 35 / 120 (29%) |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Remission) @ 16 wks | NANo | Incidence 61 / 130 (47%) | Incidence 80 / 120 (67%) |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Remission: Maintenance of remission) @ 48 wks | NANo | Incidence 79 / 130 (61%) | Incidence 102 / 120 (85%) |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | HR QoL: Global Assessment) @ 12 wks | NAYes | F: Mean, 44.2 P: 0.032 | F: Mean, 30.3 P: 0.032 |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Relapse rate) @ 4 wks | NAYes | Incidence 20 / 168 (12%) | Incidence 31 / 170 (18%) |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Relapse rate) @ 16 wks | NAYes | Incidence 57 / 168 (34%) | Incidence 102 / 170 (60%) |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Relapse rate) @ 48 wks | NAYes | Incidence 77 / 168 (46%) | Incidence 136 / 170 (80%) |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | HR QoL (IBDQ) @ 12 wks | NAYes | Incidence 123 / 168 (73%)B: 185F: Mean, 181 P: <0.01F-B: Mean, 51.6 (SD, 31)G1-G2: -7.8 | Incidence 80 / 171 (46.9%)B: 178F: Mean, 163 P: <0.01F-B: Mean, 43.8 (SD, 35)G1-G2: -7.8 P: <0.01 |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | HR QoL (IBDQ) @ 48 wks | NAYes | Incidence 120 / 168 (71.3%)B: Mean, 185F: Mean, 181 P: <0.001F-B: Mean, 53.9 (SD, 33.6)G1-G2: -18.4 | Incidence 68 / 171 (40%)B: Mean, 178F: Mean, 157 P: <0.001F-B: Mean, 35.5 (SD, 40.3)G1-G2: -18.4 P: <0.001 |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | HR QoL (SF-36, MCS) @ 12 wks | NAYes | B: Mean, 49.5F: Mean, 49.5 P: <0.01F-B: Mean, 8.6 (SD, 10.5)G1-G2: -0.6 | B: Mean, 49F: Mean, 44.5 P: <0.01F-B: Mean, 8 (SD, 11)G1-G2: -0.6 P: NS |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | HR QoL (SF-36, MCS) @ 48 wks | NAYes | B: Mean, 49.5F: Mean, 50 P: <0.001F-B: Mean, 12.6 (SE, 9.4)G1-G2: -5.8 | B: Mean, 49F: Mean, 44 P: <0.001F-B: Mean, 6.8 (SE, 9.5)G1-G2: -5.8 P: <0.001 |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | HR QoL (SF-36, PCS) @ 12 wks | NAYes | B: Mean, 46.5F: Mean, 46 P: 0.011F-B: Mean, 12.5 (SD, 8.5)G1-G2: -3.7 | B: Mean, 45.5F: Mean, 43 P: 0.011F-B: Mean, 8.8 (SD, 8.9)G1-G2: -3.7 P: <0.01 |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | HR QoL (SF-36, PCS) @ 48 wks | NAYes | B: Mean, 46.5F: Mean, 46 P: <0.001F-B: Mean, 12.6 (SD, 9.4)G1-G2: -5.8 | B: Mean, 45.5F: Mean, 41.5 P: <0.001F-B: Mean, 6.8 (SD, 9.5)G1-G2: -5.8 P: <0.001 |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | Median time to loss of remission  | NANR | Event rate 336 days | Event rate 86 days |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Relapse rate) @ 24 wks | NANo | Incidence 16 / 35 (46%) | Incidence 15 / 33 (45%) P: 0.58 |
| Feagan, 200781 | NatalizumabRoute: IVDose: 300 mg every 4 wks | PlaceboRoute: IVDose: NA every 4 wks | CDAI (Relapse rate) @ 48 wks | NANo | Incidence 18 / 35 (51%) | Incidence 21 / 33 (64%) P: 0.16 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | CDAI (Response: 100 pt drop) @ 18 wks | NAYes | Incidence 135 / 216 (63%) | Incidence 76 / 212 (36%) |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | CDAI (Remission: CDAI < 150) @ 18 wks | NAYes | Incidence 103 / 216 (48%) | Incidence 60 / 212 (29%) |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (IBDQ) @ 18 wks | NAYes | F: Mean, 175.7 (SD, 29.24) P: 0.001 | F: Mean, 167.9 (SD, 32.19) P: 0.001 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (IBDQ remission (total score ≥170 pts)) @ 18 wks | NAYes | Incidence 99 / 213 (46.5%) | Incidence 55 / 210 (26.2%) P: 0.001 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (IBDQ response (≥ 16 pt increase)) @ 18 wks | NAYes | Incidence 129 / 213 (61%) | Incidence 90 / 210 (43%) |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (IBDQ response (≥ 16 pt increase)) @ 18 wks | NAYes | Incidence 129 / 216 (60%) | Incidence 90 / 212 (43%) |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (SF-36 MCS response (+3.9 pts)) @ 18 wks | NAYes | Incidence 92 / 208 (44.2%) | Incidence 67 / 207 (32.4%) P: 0.016 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (SF-36 MCS) @ 18 wks | NAYes | F: Mean, 46.9 (SD, 11.53) P: 0.001 | F: Mean, 45.2 (SD, 11.83) P: 0.001 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (SF-36 PCS response (+4.1 pts)) @ 18 wks | NAYes | Incidence 107 / 209 (51.2%) | Incidence 70 / 207 (33.8%) P: 0.001 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (SF-36 PCS) @ 18 wks | NAYes | F: Mean, 48.1 (SD, 8.17) P: 0.014 | F: Mean, 46.4 (SD, 7.69) P: 0.014 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (WPAI:CD Presenteeism) @ 18 wks | NAYes | F-B: Mean, 4.3 (SD, 23.6) P: NS | F-B: Mean, 13.7 (SD, 30.5) P: <0.001G1-G2: Mean, 9.4 (95% CI, 2.1 to 16.8) P: 0.013 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (WPAI:CD Daily activity impairment) @ 18 wks | NAYes | F-B: Mean, 5.1 (SD, 29.4) P: <0.05G1-G2: Mean,  | F-B: Mean, 15.3 (SD, 30) P: <0.001G1-G2: Mean, 10.2 (95% CI, 4.3 to 16.1) |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (WPAI:CD Absenteeism) @ 18 wks | NAYes | F-B: Mean, 4 (SD, 25.1) P: NSG1-G2: Mean,  | F-B: Mean, 10.3 (SD, 23.8) P: <0.001G1-G2: Mean, 6.3 (95% CI, -0.5 to 13.2) P: 0.07 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (WPAI:CD Overall work impairment) @ 18 wks | NAYes | F-B: Mean, 5.1 (SD, 24.4) P: <0.05G1-G2: Mean,  | F-B: Mean, 16.1 (SD, 32.2) P: <0.001G1-G2: Mean, 11 (95% CI, 2.8 to 19.2) P: 0.01 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (EQ-5D VAS response (9.2-pt increase)) @ 18 wks | NAYes | Incidence 115 / 211 (57.2%) | Incidence 77 / 203 (37.9%) |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (EQ-5D VAS) @ 18 wks | NAYes | F: Mean, 74.6 (SD, 17.13) P: 0.002 | F: Mean, 70.2 (SD, 18.07) P: 0.002 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (Normal life) @ 18 wks | NAYes | Incidence 46 / 215 (21.4%) | Incidence 27 / 210 (12.9%) P: 0.019 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | HR QoL (QALY) @ 18 wks | NAYes | F: Mean, 0.25 (SD, 0.1) P: 0.001 | F: Mean, 0.21 (SD, 0.11) P: 0.001 |
| Schreiber, 200784 | Certolizumab pegolRoute: SCDose: 400 mg every 4 wks | PlaceboRoute: SCDose: NA every 4 wks | Perianal disease (Complete fistula closure) @ 18 wks | NAYes | Incidence 15 / 28 (54%) | Incidence 13 / 30 (43%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 100pt drop) @ 4 wks | NAYes | Incidence 15 / 19 (79%) | Incidence 12 / 18 (67%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 100pt drop) @ 16 wks | NAYes | Incidence 18 / 19 (94%) | Incidence 11 / 18 (61%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 100pt drop) @ 52 wks | NAYes | Incidence 15 / 19 (79%) | Incidence 10 / 18 (56%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 70pt drop) @ 4 wks | NAYes | Incidence 17 / 19 (89%) | Incidence 16 / 18 (89%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 70pt drop) @ 16 wks | NAYes | Incidence 18 / 19 (95%) | Incidence 15 / 18 (83%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 70pt drop) @ 52 wks | NAYes | Incidence 15 / 19 (79%) | Incidence 13 / 18 (72%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Absolute CDAI) @ 52 wks | NAYes | F-B: Mean, -150.8 (95% CI, -202 to -99.8)G1-G2: 31.2 | F-B: Mean, -119.6 (95% CI, -174 to -65.1)G1-G2: 31.2 P: <0.05 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Remission: CDAI < 150) @ 4 wks | NAYes | Incidence 16 / 19 (85%) | Incidence 10 / 18 (55%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Remission: CDAI < 150) @ 16 wks | NAYes | Incidence 17 / 19 (91%) | Incidence 9 / 18 (51%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Remission: CDAI < 150) @ 52 wks | NAYes | Incidence 15 / 19 (79%) | Incidence 8 / 18 (44%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | HR QoL (IBDQ) @ 16 wks | NAYes | B: Mean, 187F: Mean, 177-10 | B: Mean, 188F: Mean, 171-17 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 187F: Mean, 178.4-8.6 | B: Mean, 188F: Mean, 162.4-25.6 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | HR QoL (IBDQ) @ 4 wks | NAYes | B: Mean, 187F: Mean, 181 P: NS-6 | B: Mean, 188F: Mean, 179 P: NS-9 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 1 wks | Steroid free (completely discontinued steroids) @ 52 wks | NAYes | Incidence 4 / 6 (67%) | Incidence 4 / 7 (56%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 100pt drop) @ 4 wks | NAYes | Incidence 16 / 18 (89%) | Incidence 12 / 18 (67%) P: NS |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 100pt drop) @ 16 wks | NAYes | Incidence 15 / 18 (84%) | Incidence 11 / 18 (61%) P: NS |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 100pt drop) @ 52 wks | NAYes | Incidence 16 / 18 (89%) | Incidence 10 / 18 (56%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 70pt drop) @ 4 wks | NAYes | Incidence 18 / 18 (100%) | Incidence 16 / 18 (89%) P: NS |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 70pt drop) @ 16 wks | NAYes | Incidence 17 / 18 (95%) | Incidence 15 / 18 (83%) P: NS |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Response: 70pt drop) @ 52 wks | NAYes | Incidence 16 / 18 (89%) | Incidence 13 / 18 (72%) P: NS |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Remission: CDAI < 150) @ 4 wks | NAYes | Incidence 16 / 18 (89%) | Incidence 10 / 18 (55%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Remission: CDAI < 150) @ 16 wks | NAYes | Incidence 15 / 18 (83%) | Incidence 9 / 18 (51%) |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Remission: CDAI < 150) @ 52 wks | NAYes | Incidence 15 / 18 (83%) | Incidence 8 / 18 (44%) P: <0.05 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | CDAI (Absolute CDAI) @ 52 wks | NAYes | F-B: Mean, -197.7 (95% CI, -248 to -147)G1-G2: 78.1 | F-B: Mean, -119.6 (95% CI, -174 to -65.1)G1-G2: 78.1 P: <0.05 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | HR QoL (IBDQ) @ 4 wks | NAYes | B: Mean, 191F: Mean, 187 P: NS-4 | B: Mean, 188F: Mean, 179 P: NS-9 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | HR QoL (IBDQ) @ 16 wks | NAYes | B: Mean, 191F: Mean, 186-5 | B: Mean, 188F: Mean, 171-17 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 191F: Mean, 185.6-5.4 | B: Mean, 188F: Mean, 162.4-25.6 |
| Sandborn, 200783 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 1 wks | Steroid free (completely discontinued steroids) @ 52 wks | NAYes | Incidence 7 / 8 (88%) | Incidence 4 / 7 (56%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 70 pt drop) @ 22 wks | NAYes | Incidence 93 / 172 (54.1%) | Incidence 48 / 170 (28.2%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 70 pt drop) @ 52 wks | NAYes | Incidence 74 / 172 (43%) | Incidence 30 / 170 (17.6%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Absolute CDAI) @ 2 wks | NAYes | B: Mean, 155F: Mean, 150F-B: -5 | B: Mean, 170F: Mean, 175 F-B: 5 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Absolute CDAI) @ 16 wks | NAYes | B: Mean, 155F: Mean, 135 F-B: -20 | B: Mean, 170F: Mean, 165 F-B: -5 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Absolute CDAI) @ 52 wks | NAYes | B: Mean, 155F: Mean, 100F-B: -55 | B: Mean, 170F: Mean, 135F-B: -35 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 100 pt drop) @ 22 wks | NAYes | Incidence 89 / 172 (51.7%) | Incidence 45 / 170 (26.5%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 100 pt drop) @ 52 wks | NAYes | Incidence 71 / 172 (41.3%) | Incidence 28 / 170 (16.5%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Remission: CDAI < 150) @ 2 wks | NAYes | Incidence 98 / 172 (57%) | Incidence 56 / 170 (33%) P: 0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Remission: CDAI < 150) @ 16 wks | NAYes | Incidence 74 / 172 (43%) | Incidence 36 / 170 (21%) P: 0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Remission: CDAI < 150) @ 52 wks | NAYes | Incidence 62 / 172 (36%) | Incidence 20 / 170 (12%) P: 0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Zung Self-Rating Depression Scale) @ 8 wks | NAYes | B: Mean, 44.9 (SD, 10.7)F: Mean, 43.4 (SD, 11)F-B: -1.5 | B: Mean, 46.1 (SD, 11.9)F: Mean, 47.4 (SD, 12.8)F-B: 1.3 P: <0.01 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Zung Self-Rating Depression Scale) @ 52 wks | NAYes | B: Mean, 44.9 (SD, 10.7)F: Mean, 43.7 (SD, 11) F-B: -1.2 | B: Mean, 46.1 (SD, 11.9)F: Mean, 47.9 (SD, 13.1) F-B: 1.8 P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (FACIT-Fatigue Scale Scores) @ 8 wks | NAYes | B: Mean, 35.6 (SD, 10.6)F: Mean, 38.2 (SD, 10.5)F-B: 2.6 | B: Mean, 34.6 (SD, 11.3)F: Mean, 33.4 (SD, 12.2) F-B: -1.2 P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (FACIT- Fatigue Scale Scores) @ 52 wks | NAYes | B: Mean, 35.6 (SD, 10.6)F: Mean, 36.8 (SD, 11.2)F-B: 1.2 | B: Mean, 34.6 (SD, 11.3)F: Mean, 32.5 (SD, 12.6) F-B: -2.1 P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (IBDQ) @ 8 wks | NAYes | B: Mean, 171F: Mean, 175 P: <0.001 F-B: 4 | B: Mean, 168F: Mean, 160 P: <0.001 F-B: -8 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 171F: Mean, 177 P: <0.0001 F-B: 6 | B: Mean, 168F: Mean, 159 P: <0.0001 F-B: -9 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 MCS) @ 8 wks | NAYes | B: Mean, 46.2 (SD, 10.4)F: Mean, 48.4 (SD, 10.7)F-B: 2.2 | B: Mean, 47.4 (SD, 10.4)F: Mean, 46.2 (SD, 11)F-B: -1.2 P: NS |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 MCS) @ 52 wks | NAYes | B: Mean, 46.2 (SD, 10.4)F: Mean, 48.7 (SD, 10.5)F-B: 2.5 | B: Mean, 47.4 (SD, 10.4)F: Mean, 45.9 (SD, 11.2) F-B: -1.5 P: <0.05 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36, MCS - +5 pt increase) @ 52 wks | NAYes | Incidence 94 / 140 (67%) | Incidence 57 / 106 (54%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 PCS) @ 8 wks | NAYes | B: Mean, 44.5 (SD, 7.8)F: Mean, 46.9 (SD, 8.6) F-B: 2.4 | B: Mean, 44.3 (SD, 8.9)F: Mean, 44.5 (SD, 9) F-B: 0.2 P: <0.01 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 PCS) @ 52 wks | NAYes | B: Mean, 44.5 (SD, 7.8)F: Mean, 47.5 (SD, 8.5)F-B: 3 | B: Mean, 44.3 (SD, 8.9)F: Mean, 45.3 (SD, 8.6) F-B: 1 P: <0.05 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36, PCS - +5 pt increase) @ 52 wks | NAYes | Incidence 108 / 140 (77%) | Incidence 65 / 106 (61%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Abdominal pain VAS) @ 8 wks | NAYes | B: Mean, 27.8 (SD, 19.4)F: Mean, 24 (SD, 21.2)F-B: -3.8 | B: Mean, 28.3 (SD, 19.5)F: Mean, 32.9 (SD, 24.5) F-B: 4.6 P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Abdominal pain VAS) @ 52 wks | NA NA | B: Mean, 27.8 (SD, 19.4)F: Mean, 23.9 (SD, 22.4) F-B: -3.9 | B: Mean, 28.3 (SD, 19.5)F: Mean, 36 (SD, 26.5) F-B: 7.7 P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Perianal disease (Mean number of draining fistulas/ day) @ 52 wks | NANo | Event rate 0.93 events among 1 d | Event rate 1.15 events among 1 d |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Steroid free (corticosteroid-free remission (CDAI < 150)) @ 22 wks | NAYes | Incidence 20 / 58 (35%) | Incidence 2 / 66 (3%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 2 wks | PlaceboRoute: SCDose: NA every 2 wks | Steroid free (corticosteroid-free remission (CDAI < 150)) @ 52 wks | NAYes | Incidence 17 / 58 (29%) | Incidence 4 / 66 (6%) |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 70 pt drop) @ 22 wks | NAYes | Incidence 88 / 157 (56.1%) | Incidence 48 / 170 (28.2%) P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 70 pt drop) @ 52 wks | NAYes | Incidence 77 / 157 (49%) | Incidence 30 / 170 (17.6%) P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Absolute CDAI) @ 2 wks | NAYes | B: Mean, 165F: Mean, 160 F-B: -5 | B: Mean, 170F: Mean, 175 F-B: 5 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Absolute CDAI) @ 16 wks | NAYes | B: Mean, 165F: Mean, 120 F-B: -45 | B: Mean, 170F: Mean, 165 F-B: -5 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Absolute CDAI) @ 52 wks | NAYes | B: Mean, 165F: Mean, 80 F-B: -85 | B: Mean, 170F: Mean, 135 F-B: -35 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 100 pt drop) @ 22 wks | NAYes | Incidence 82 / 157 (52.2%) | Incidence 45 / 170 (26.5%) P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Response: 100 pt drop) @ 52 wks | NAYes | Incidence 75 / 157 (47.8%) | Incidence 28 / 170 (16.5%) P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Remission: CDAI < 150) @ 2 wks | NAYes | Incidence 66 / 157 (42%) | Incidence 56 / 170 (33%) P: NS |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Remission: CDAI < 150) @ 16 wks | NAYes | Incidence 71 / 157 (45%) | Incidence 36 / 170 (21%) P: 0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | CDAI (Remission: CDAI < 150) @ 52 wks | NAYes | Incidence 65 / 157 (41%) | Incidence 20 / 170 (12%) P: 0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (FACIT- Fatigue Scale Scores) @ 8 wks | NAYes | B: Mean, 34.2 (SD, 11.2)F: Mean, 34.6 (SD, 11.5) F-B: 0.4 | B: Mean, 34.6 (SD, 11.3)F: Mean, 33.4 (SD, 12.2) F-B: -1.2 P: NS |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (FACIT- Fatigue Scale Scores) @ 52 wks | NAYes | B: Mean, 34.2 (SD, 11.2)F: Mean, 35 (SD, 12.7) F-B: 0.8 | B: Mean, 34.6 (SD, 11.3)F: Mean, 32.5 (SD, 12.6) F-B: -2.1 P: <0.05 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (IBDQ) @ 8 wks | NAYes | B: Mean, 167F: Mean, 170 P: <0.05 F-B: 3 | B: Mean, 168F: Mean, 160 P: <0.05 F-B: -8 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 167F: Mean, 171 P: <0.01 F-B: 4 | B: Mean, 168F: Mean, 159 P: <0.01 F-B: -9 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Zung Self-Rating Depression Scale) @ 8 wks | NAYes | B: Mean, 47 (SD, 11.2)F: Mean, 46.1 (SD, 11.5)F-B: -0.9 | B: Mean, 46.1 (SD, 11.9)F: Mean, 47.4 (SD, 12.8) F-B: 1.3 P: NS |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Zung Self-Rating Depression Scale) @ 52 wks | NAYes | B: Mean, 47 (SD, 11.2)F: Mean, 45.9 (SD, 12.3) F-B: -1.1 | B: Mean, 46.1 (SD, 11.9)F: Mean, 47.9 (SD, 13.1) F-B: 1.8 P: <0.05 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 PCS) @ 8 wks | NAYes | B: Mean, 43.7 (SD, 8.4)F: Mean, 46 (SD, 8.6) F-B: 2.3 | B: Mean, 44.3 (SD, 8.9)F: Mean, 44.5 (SD, 9) F-B: 0.2 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 PCS) @ 52 wks | NAYes | B: Mean, 43.7 (SD, 8.4)F: Mean, 47.1 (SD, 9.4) F-B: 3.4 | B: Mean, 44.3 (SD, 8.9)F: Mean, 45.3 (SD, 8.6) F-B: 1 P: NS |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 MCS) @ 8 wks | NAYes | B: Mean, 45.7 (SD, 9.3)F: Mean, 46.1 (SD, 11.9) F-B: 0.4 | B: Mean, 47.4 (SD, 10.4)F: Mean, 46.2 (SD, 11) F-B: -1.2 P: NS |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (SF-36 MCS) @ 52 wks | NAYes | B: Mean, 45.7 (SD, 9.3)F: Mean, 46.5 (SD, 12.4) F-B: 0.8 | B: Mean, 47.4 (SD, 10.4)F: Mean, 45.9 (SD, 11.2) F-B: -1.5 P: NS |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Abdominal pain VAS) @ 8 wks | NAYes | B: Mean, 31 (SD, 18.7)F: Mean, 27.8 (SD, 23.1) F-B: -3.2 | B: Mean, 28.3 (SD, 19.5)F: Mean, 32.9 (SD, 24.5) F-B: 4.6 P: <0.05 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | HR QoL (Abdominal pain VAS) @ 52 wks | NA NA | B: Mean, 31 (SD, 18.7)F: Mean, 26.7 (SD, 24.2) F-B: -4.3 | B: Mean, 28.3 (SD, 19.5)F: Mean, 36 (SD, 26.5) F-B: 7.7 P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Perianal disease (Mean number of draining fistulas/day) @ 52 wks | NANo | Event rate 0.65 events among 1 d | Event rate 1.15 events among 1 d |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Steroid free (corticosteroid-free remission (CDAI < 150)) @ 22 wks | NAYes | Incidence 22 / 74 (30%) | Incidence 2 / 66 (3%) P: <0.001 |
| Colombel, 200782 | AdalimumabRoute: SCDose: 40 mg every 1 wks | PlaceboRoute: SCDose: NA every 2 wks | Steroid free (corticosteroid-free remission (CDAI < 150)) @ 52 wks | NAYes | Incidence 17 / 74 (23%) | Incidence 4 / 66 (6%) P: 0.008 |
| Lemann, 200598 | AzathioprineRoute: OralDose: as taken before enrollment every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI > 250, a CDAI between 150-250 on 3 consecutive wks with an increase ≥75 pts, or the need for surgery (with the exception of limited perianal surgery)) @ 78 wks | NAYes | Incidence 3 / 40 (7.9%) | Incidence 9 / 43 (21.3%) P: 0.195 |
| Lemann, 200598 | AzathioprineRoute: OralDose: as taken before enrollment every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Remission duration) | NAYes | Event rate 17.3 months | Event rate 15.9 months |
| Prantera, 2005115 | Mesalamine (Asacol)Route: OralDose: 4 g | PlaceboRoute: UnknownDose: NA | CDAI (Remission: CDAI < 150) @ 52 wks | NANR | Incidence 3 / 23 (13%) | Incidence 3 / 17 (18%) |
| Hanauer, 2005106 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI≥150 plus increase of ≥60 pts or clinical deterioration) @ 13 wks | NA NA | Incidence 14 / 55 (25%) | Incidence 21 / 55 (38%) |
| Hanauer, 2005106 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI≥150 plus increase of ≥60 pts or clinical deterioration) @ 52 wks | NAYes | Incidence 26 / 55 (47%) | Incidence 32 / 55 (58%) |
| Vilien, 2004101 | Discontinued azathioprine | AzathioprineRoute: UnknownDose: NR every 1 d | CDAI (Relapse rate: CDAI ≥ 75 increase and CDAI >150 or any increased disease activity requiring new medical or surgical treatment) @ 52 wks | NANR | Incidence 8 / 15 (53%) | Incidence 2 / 14 (14%) |
| Mantzaris, 2003113 | Mesalamine (Salofalk)Route: UnknownDose: 1 g every 8 hrs | BudesonideRoute: UnknownDose: 6 mg every 1 d | CDAI (Relapse rate: >150 and >100 from baseline) @ 52 wks | NANR | Incidence 23 / 28 (82%) | Incidence 16 / 29 (55%) P: 0.045 |
| Mantzaris, 2003113 | Mesalamine (Salofalk)Route: UnknownDose: 1 g every 8 hrs | BudesonideRoute: UnknownDose: 6 mg every 1 d | HR QoL (IBDQ) @ 52 wks | NANR | G1-G2: Mean, 113 (SD, 33) | G1-G2: Mean, 150 (SD, 44; 15.93 to 58.07) |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Absolute CDAI) @ 16 wks | NAYes | F-B: Median, -42 | F-B: Median, -16G1-G2: 26 P: 0.004 |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Absolute CDAI) @ 40 wks | NAYes | F-B: Median, -40 | F-B: Median, -15G1-G2: 25 P: 0.04 |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (IBDQ) @ 16 wks | NAYes | F-B: Median, 14 | F-B: Median, 4G1-G2: -10 P: 0.002 |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (IBDQ) @ 40 wks | NAYes | F-B: Median, 10 | F-B: Median, 5G1-G2: -5 |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Need for surgery (All surgeries) @ 40 wks | NAYes | Event rate 49 events among 100 persons | Event rate 100 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Need for surgery (All patients and surgeries) @ 40 wks | NAYes | Event rate 65 events among 100 persons | Event rate 126 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Need for surgery (Major surgeries) @ 40 wks | NAYes | Event rate 2 events among 100 persons | Event rate 16 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Need for surgery (Major surgeries) @ 40 wks | NAYes | Event rate 2 events among 100 persons | Event rate 11 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Need for surgery (Inpatient surgeries and procedures) @ 40 wks | NAYes | Event rate 16 events among 100 persons | Event rate 55 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Need for surgery (Inpatient surgeries and procedures) @ 40 wks | NAYes | Event rate 7 events among 100 persons | Event rate 41 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Need for surgery (not specified) @ 40 wks | NAYes | Incidence 1 / 96 (1%) | Incidence 0 / 99 (0%) |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Number of hospitalizations (mean number of hospitalizations per 100 patients) @ 40 wks | NAYes | Event rate 19 events among 100 persons | Event rate 32 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Number of hospitalizations (mean number of hospitalizations per 100 patients) @ 40 wks | NAYes | Incidence 7 / 96 (7.3%)Event rate 11 events among 100 persons | Incidence 18 / 99 (18.2%)Event rate 31 events among 100 persons |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Number of hospitalizations (mean number of hospitalization days) @ 40 wks | NAYes | 0.5  | 2.5  |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Number of hospitalizations (mean number of hospitalization days) @ 40 wks | NAYes | 1.6  | 2.3  |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Perianal disease (50% fistula closure) @ 40 wks | NAYes | Incidence 9 / 43 (21%) | Incidence 7 / 44 (16%) |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Perianal disease (50% fistula closure) @ 40 wks | NAYes | Incidence 46 / 91 (42%) | Incidence 23 / 98 (23%) P: 0.001 |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Perianal disease (Complete fistula closure) @ 40 wks | NAYes | Incidence 33 / 91 (36%) | Incidence 19 / 98 (19%) P: 0.009 |
| Sands, 200487 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Perianal disease (Loss of response, defined as recrudescence of draining fistulas, the need for a change in medication, or need for additional medication, the need for surgery, or discontinuation of study due to lack of efficacy) @ 40 wks | NAYes | Incidence 40 / 96 (42%) | Incidence 61 / 99 (62%) |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Remission: CDAI < 150) @ 30 wks | NA NA | Incidence 44 / 113 (39%) | Incidence 23 / 110 (21%) P: 0.003 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Remission: CDAI < 150) @ 52 wks | NAYes | Incidence 34 / 113 (30%) | Incidence 16 / 110 (15%) P: 0.007 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Response: 70 pt drop & at least 25% reduction) @ 28 wks | NAYes | Incidence 62 / 113 (55%) | Incidence 30 / 110 (27%) P: 0.002 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Response: 70 pt drop & at least 25% reduction) @ 52 wks | NAYes | Incidence 44 / 113 (39%) | Incidence 20 / 110 (18%) P: 0.001 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 MCS) @ 30 wks | NAYes | F-B: Mean, 4.6G1-G2: -1.7 | F-B: Mean, 2.9G1-G2: -1.7 P: NS |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 MCS) @ 52 wks | NAYes | F-B: Mean, 5.1G1-G2: -3.1 | F-B: Mean, 2G1-G2: -3.1 P: NS |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 PCS) @ 28 wks | NAYes | F-B: Mean, 7.3G1-G2: -4.2 | F-B: Mean, 3.1G1-G2: -4.2 P: <0.01 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 PCS) @ 52 wks | NAYes | F-B: Mean, 6.1G1-G2: -3.6 | F-B: Mean, 2.5G1-G2: -3.6 P: <0.05 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (IBDQ) @ 28 wks | NAYes | B: Mean, 170 (SD, 26)F-B: Mean, 27.1G1-G2: -13.1 | B: Mean, 170 (SD, 29)F-B: Mean, 14G1-G2: -13.1 P: <0.05 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 170 (SD, 26)F-B: Mean, 22.1G1-G2: -13.2 | B: Mean, 170 (SD, 29)F-B: Mean, 8.9G1-G2: -13.2 P: <0.05 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 5 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | Steroid free (Steroid-free remission) @ 52 wks | NAYes | OR: 4.2 (1.5 to 11.5) vs. main |  |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Response: 70 pt drop in CDAI & at least 25% reduction) @ 28 wks | NAYes | Incidence 67 / 112 (60%) | Incidence 30 / 110 (27%) P: <0.001 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Response: 70 pt drop & at least 25% reduction) @ 52 wks | NAYes | Incidence 53 / 112 (47%) | Incidence 20 / 110 (18%) P: <0.001 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Remission: CDAI < 150) @ 30 wks | NA NA | Incidence 50 / 112 (45%) | Incidence 23 / 110 (21%) P: 0.002 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | CDAI (Remission: CDAI < 150) @ 52 wks | NAYes | Incidence 45 / 112 (40%) | Incidence 16 / 110 (15%) P: <0.001 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 MCS) @ 30 wks | NAYes | F-B: Mean, 4.9G1-G2: -2 | F-B: Mean, 2.9G1-G2: -2 P: NS |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 MCS) @ 52 wks | NAYes | F-B: Mean, 5.8G1-G2: -3.8 | F-B: Mean, 2G1-G2: -3.8 P: <0.05 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 PCS) @ 28 wks | NAYes | F-B: Mean, 7.3G1-G2: -4.2 | F-B: Mean, 3.1G1-G2: -4.2 P: <0.01 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (SF-36 PCS) @ 52 wks | NAYes | F-B: Mean, 7.2G1-G2: -4.7 | F-B: Mean, 2.5G1-G2: -4.7 P: <0.01 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (IBDQ) @ 28 wks | NAYes | B: Mean, 168 (SD, 31)F-B: Mean, 31.7G1-G2: -17.7 | B: Mean, 170 (SD, 29)F-B: Mean, 14G1-G2: -17.7 P: <0.01 |
| Hanauer, 200286 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: IVDose: NA every 8 wks | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 168 (SD, 31)F-B: Mean, 30.2G1-G2: -21.3 | B: Mean, 170 (SD, 29)F-B: Mean, 8.9G1-G2: -21.3 P: <0.001 |
| Mahmud, 2001116 | OlsalazineRoute: OralDose: 2 g every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI >150 or 60-pt increase) @ 52 wks | NANR | Incidence 40 / 167 (24%) | Incidence 42 / 161 (26.1%) |
| Mahmud, 2001116 | OlsalazineRoute: OralDose: 2 g every 1 d | PlaceboRoute: OralDose: NA every 1 d | Clinical relapse (need for additional therapy or surgery in exceptional situations where CDAI criteria are not fulfilled) @ 52 wks | NANR | Incidence 15 / 167 (9%) | Incidence 17 / 161 (10.6%) |
| Cortot, 2001107 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: UnknownDose: NA every 1 d | CDAI (Relapse rate: >200 and 60 pt increase) @ 13 wks | NANR | Incidence 19 / 59 (32%) | Incidence 38 / 58 (65%) |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Absolute CDAI) @ 4 wks | NAYes | B: Median, 175F: Median, 105 | B: Median, 170F: Median, 160 |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Absolute CDAI) @ 16 wks | NAYes | B: Median, 175F: Median, 102 | B: Median, 170F: Median, 192 |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Absolute CDAI) @ 36 wks | NAYes | B: Median, 175F: Median, 150 | B: Median, 170F: Median, 200 |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Response: 70 pt drop) @ 4 wks | NAYes | Incidence 30 / 37 (80%) | Incidence 28 / 36 (77%) |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Response: 70 pt drop) @ 16 wks | NAYes | Incidence 27 / 37 (73%) | Incidence 21 / 36 (58%) |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Response: 70 pt drop) @ 36 wks | NAYes | Incidence 20 / 37 (53%) | Incidence 11 / 36 (30%) |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Remission: CDAI < 150) @ 4 wks | NAYes | Incidence 22 / 37 (59%) | Incidence 14 / 36 (40%) |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Remission: CDAI < 150) @ 16 wks | NAYes | Incidence 22 / 37 (60%) | Incidence 11 / 36 (30%) |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (Remission: CDAI < 150) @ 36 wks | NAYes | Incidence 14 / 37 (37%) | Incidence 7 / 36 (20%) |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | CDAI (time to loss of response) | NAYes | 48 wks | 37 wks P: 0.057 |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | HR QoL (IBDQ) @ 4 wks | NAYes | B: Median, 166F: Median, 180 | B: Median, 168F: Median, 166 |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | HR QoL (IBDQ) @ 16 wks | NAYes | B: Median, 166F: Median, 180 | B: Median, 168F: Median, 160 |
| Rutgeerts, 199985 | InfliximabRoute: IVDose: 10 mg/kg every 8 wks | PlaceboRoute: UnknownDose: NA every 8 wks | HR QoL (IBDQ) @ 36 wks | NAYes | B: Median, 166F: Median, 158 | B: Median, 168F: Median, 137 |
| Ferguson, 1998108 | Budesonide + placeboRoute: Oral + OralDose: 3 mg every 1 d + NA every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI > 150 and 60-pt increase, or any deterioration requiring a different medicine or surgery) @ 52 wks | NAYes | Incidence 12 / 26 (46%) | Incidence 16 / 27 (60%) |
| Ferguson, 1998108 | Budesonide + placeboRoute: Oral + OralDose: 3 mg every 1 d + NA every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Absolute CDAI) @ 52 wks | NAYes | B: Mean, 75F-B: Mean, 71G1-G2: -3 | B: Mean, 90F-B: Mean, 68G1-G2: -3 |
| Ferguson, 1998108 | Budesonide + placeboRoute: Oral + OralDose: 3 mg every 1 d + NA every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: Median time to relapse) | NAYes | 335 days | 310 days |
| Ferguson, 1998108 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI > 150 and 60-pt increase, or any deterioration requiring a different medicine or surgery) @ 52 wks | NAYes | Incidence 11 / 22 (48%) | Incidence 16 / 27 (60%) |
| Ferguson, 1998108 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Absolute CDAI) @ 52 wks | NAYes | B: Mean, 102F-B: Mean, 14G1-G2: 54 | B: Mean, 90F-B: Mean, 68G1-G2: 54 |
| Ferguson, 1998108 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate definition: Median time to relapse) | NAYes | 275 days | 310 days |
| Gross, 1998109 | BudesonideRoute: OralDose: 3 mg every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: CDAI<150 on 2 consecutive wks) @ 52 wks | NAYes | Incidence 56 / 84 (66.7%) | Incidence 62 / 95 (65.3%) |
| de Franchis, 1997118 | ASA + (6)-MethylprednisoloneRoute: Oral + OralDose: 1000 mg every 8 hrs + every 24 hrs | Placebo + (6)-MethylprednisoloneRoute: Oral + OralDose: NA every 8 hrs + every 24 hrs | CDAI (Relapse rate: CDAI > 150 and ≥60 pts increase, and increase in at least 2 of 3 acute phase reactants) @ 4 wks | NANR | Incidence 58 / 59 (98%)B: Mean, 70.5 (SD, 4.5) | Incidence 57 / 58 (98%)B: Mean, 71.2 (SD, 4.9) |
| de Franchis, 1997118 | ASA + (6)-MethylprednisoloneRoute: Oral + OralDose: 1000 mg every 8 hrs + every 24 hrs | Placebo + (6)-MethylprednisoloneRoute: Oral + OralDose: NA every 8 hrs + every 24 hrs | CDAI (Relapse rate: CDAI > 150 and ≥60 pts increase, and increase in at least 2 of 3 acute phase reactants) @ 16 wks | NANR | Incidence 16 / 58 (27%) | Incidence 10 / 59 (17%) |
| de Franchis, 1997118 | ASA + (6)-MethylprednisoloneRoute: Oral + OralDose: 1000 mg every 8 hrs + every 24 hrs | Placebo + (6)-MethylprednisoloneRoute: Oral + OralDose: NA every 8 hrs + every 24 hrs | CDAI (Relapse rate: CDAI > 150 and ≥60 pts increase, and increase in at least 2 of 3 acute phase reactants) @ 52 wks | NANR | Incidence 34 / 58 (58.3%) | Incidence 31 / 59 (52.2%) |
| Sutherland, 1997117 | Mesalamine (Pentasa)Route: OralDose: 750 mg every 6 hrs | PlaceboRoute: OralDose: NA every 6 hrs | CDAI (Relapse rate: CDAI>150 and ≥ 60 pts increase, or diagnosed flare up or need for steroids or hospitalization) @ 12 wks | NANo | Incidence 14 / 118 (12%) | Incidence 28 / 128 (22%) |
| Sutherland, 1997117 | Mesalamine (Pentasa)Route: OralDose: 750 mg every 6 hrs | PlaceboRoute: OralDose: NA every 6 hrs | CDAI (Relapse rate: CDAI>150 and ≥ 60 pts increase, or diagnosed flare up or need for steroids or hospitalization) @ 48 wks | NANo | Incidence 41 / 118 (35%) | Incidence 55 / 128 (43%) |
| Sutherland, 1997117 | Mesalamine (Pentasa)Route: OralDose: 750 mg every 6 hrs | PlaceboRoute: OralDose: NA every 6 hrs | CDAI (Absolute CDAI) @ 48 wks | NANo | B: Mean, 74.5 (SE, 3.7)F: Mean, 91.5F-B: Mean, 17 P: 0.02G1-G2: 18 | B: Mean, 75.2 (SE, 4)F: Mean, 110F-B: Mean, 35 P: 0.001G1-G2: 18 |
| Sutherland, 1997117 | Mesalamine (Pentasa)Route: OralDose: 750 mg every 6 hrs | PlaceboRoute: OralDose: NA every 6 hrs | HR QoL (IBDQ) @ 48 wks | NANo | B: Mean, 193.4 (SE, 1.9)F: Mean, 180-13.4 | B: Mean, 193 (SE, 1.8)F: Mean, 179-14 |
| Sutherland, 1997117 | Mesalamine (Pentasa)Route: OralDose: 750 mg every 6 hrs | PlaceboRoute: OralDose: NA every 6 hrs | Time to relapse (not specified) | NANo | 119 days | 109 days |
| Lofberg, 1996110 | BudesonideRoute: OralDose: 3 mg every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: CDAI > 150 and ≥ 60 pt increase) @ 12 wks | NANR | Incidence 14 / 31 (45%) | Incidence 12 / 27 (44%) |
| Lofberg, 1996110 | BudesonideRoute: OralDose: 3 mg every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: CDAI > 150 and ≥ 60 pt increase) @ 52 wks | NANR | Incidence 23 / 31 (74%) | Incidence 17 / 27 (63%) |
| Lofberg, 1996110 | BudesonideRoute: OralDose: 3 mg every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Median time to relapse) | NANR | 175 days | 146 days |
| Lofberg, 1996110 | BudesonideRoute: OralDose: 6 mg every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: CDAI > 150 and ≥ 60 pt increase) @ 12 wks | NANR | Incidence 6 / 32 (19%) | Incidence 12 / 27 (44%) |
| Lofberg, 1996110 | BudesonideRoute: OralDose: 6 mg every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: CDAI > 150 and ≥ 60 pt increase) @ 52 wks | NANR | Incidence 19 / 32 (59%) | Incidence 17 / 27 (63%) |
| Lofberg, 1996110 | BudesonideRoute: OralDose: 6 mg every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Median time to relapse) | NANR | 271 days | 146 days |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 3 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Median time to relapse ([CDAI ≥150 + 60 pt increase] OR withdrawn because of medical or surgical treatment)) | NAYes | 124 days | 39 days |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 3 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI ≥150 and ≥ 60-pt increase or medical or surgical intervention) @ 52 wks | NAYes | Incidence 23 / 33 (70%) | Incidence 24 / 36 (67%) |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 3 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Absolute CDAI) @ 12 wks | NA NA | B: Mean, 96 (SD, 40)F: Mean, 155 (SD, 88) P: NSF-B: 59 | B: Mean, 115 (SD, 40)F: Mean, 197 (SD, 99) P: NSF-B: 82 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 3 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Absolute CDAI) @ 52 wks | NAYes | B: Mean, 96 (SD, 40)F: Mean, 209 (SD, 106) P: NSF-B: 113 | B: Mean, 115 (SD, 40)F: Mean, 210 (SD, 119) P: NSF-B: 95 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 3 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | HR QoL (IBDQ) @ 12 wks | NAYes | B: Mean, 185 (SD, 21)F: Mean, 170 (SD, 39) P: NS-15 | B: Mean, 181 (SD, 19)F: Mean, 154 (SD, 35) P: NSF-B: -27 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 3 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 185 (SD, 21)F: Mean, 156 (SD, 39) P: NSF-B: -29 | B: Mean, 181 (SD, 19)F: Mean, 150 (SD, 38) P: NSF-B: -31 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Absolute CDAI) @ 12 wks | NA NA | B: Mean, 102 (SD, 36)F: Mean, 141 (SD, 87) P: NSF-B: 39 | B: Mean, 115 (SD, 40)F: Mean, 197 (SD, 99) P: NSF-B: 82 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Absolute CDAI) @ 52 wks | NAYes | B: Mean, 102 (SD, 36)F: Mean, 182 (SD, 128) P: NSF-B: 80 | B: Mean, 115 (SD, 40)F: Mean, 210 (SD, 119) P: NS95 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | CDAI (Relapse rate: CDAI ≥150 and ≥ 60-pt increase or medical or surgical intervention) @ 52 wks | NAYes | Incidence 22 / 36 (61%) | Incidence 24 / 36 (67%) |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | Median time to relapse ([CDAI ≥150 + 60 pt increase] OR withdrawn because of medical or surgical treatment) | NAYes | 178 days | 39 days P: 0.024 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | HR QoL (IBDQ) @ 12 wks | NAYes | B: Mean, 184 (SD, 24)F: Mean, 172 (SD, 35) P: NSF-B: -12 | B: Mean, 181 (SD, 19)F: Mean, 154 (SD, 35) P: NSF-B: -27 |
| Greenberg, 1996111 | BudesonideRoute: OralDose: 6 mg every 1 d | PlaceboRoute: OralDose: NA every 1 d | HR QoL (IBDQ) @ 52 wks | NAYes | B: Mean, 184 (SD, 24)F: Mean, 161 (SD, 36) P: NSF-B: -23 | B: Mean, 181 (SD, 19)F: Mean, 150 (SD, 38) P: NSF-B: -31 |
| Thomson, 1995120 | MesalamineRoute: OralDose: 1.5 g every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Relapse rate: CDAI>150 and ≥ 60 pt increase (colitis/ ileocolitis only)) @ 4 wks | NAYes | Incidence 10 / 102 (10%) | Incidence 15 / 105 (14%) |
| Thomson, 1995120 | MesalamineRoute: OralDose: 1.5 g every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Relapse rate: CDAI>150 and ≥ 60 pt increase (colitis/ ileocolitis only)) @ 12 wks | NAYes | Incidence 13 / 102 (13%) | Incidence 18 / 105 (17%) |
| Thomson, 1995120 | MesalamineRoute: OralDose: 1.5 g every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Relapse rate: CDAI>150 and ≥ 60 pt increase (colitis/ ileocolitis only)) @ 52 wks | ActiveYesYes | Incidence 28 / 102 (27%)HR: 0.694 (0.289 to 1.666)P: 0.4501 vs. main | Incidence 33 / 105 (31%) |
| Thomson, 1995120 | MesalamineRoute: OralDose: 1.5 g every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Relapse rate: CDAI>150 and ≥ 60 pt increase (ileitis only)) @ 4 wks | NAYes | Incidence 4 / 36 (12%) | Incidence 3 / 43 (8%) P: NS |
| Thomson, 1995120 | MesalamineRoute: OralDose: 1.5 g every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI Relapse rate: CDAI>150 and ≥ 60 pt increase (ileitis only)) @ 12 wks | NAYes | Incidence 6 / 36 (18%) | Incidence 8 / 43 (19%) P: NS P: NS |
| Thomson, 1995120 | MesalamineRoute: OralDose: 1.5 g every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Relapse rate: CDAI>150 and ≥ 60 pt increase (ileitis only)) @ 52 wks | NAYes | Incidence 14 / 36 (40%)HR: 0.433 (0.1 to 1.878)P: 0.2634 vs. main | Incidence 10 / 43 (23%) P: NS |
| Candy, 199553 | Placebo + prednisoloneRoute: Oral + OralDose: NA + 1 mg/kg every 1 d | Azathioprine + prednisoloneRoute: Oral + OralDose: 2.5 mg/kg every 1 d + 1 mg/kg every 1 d | CDAI (Absolute CDAI) @ 64 wks | NAYes | B: Median, 301 (IQR, 264 to 358)F-B: Median, -191.5 (IQR, 45.5 to 256.5) P: 0.06G1-G2: 141.5 | B: Median, 282 (IQR, 240 to 356)F-B: Median, -50 (IQR, 8 to 222) |
| Candy, 199553 | Placebo + prednisoloneRoute: Oral + OralDose: NA + 1 mg/kg every 1 d | Azathioprine + prednisoloneRoute: Oral + OralDose: 2.5 mg/kg every 1 d + 1 mg/kg every 1 d | CDAI (Remission: CDAI < 150) @ 12 wks | NAYes | Incidence 19 / 30 (63%) | Incidence 24 / 33 (73%) P: 0.6 |
| Candy, 199553 | Placebo + prednisoloneRoute: Oral + OralDose: NA + 1 mg/kg every 1 d | Azathioprine + prednisoloneRoute: Oral + OralDose: 2.5 mg/kg every 1 d + 1 mg/kg every 1 d | CDAI (Remission: CDAI < 150) @ 60 wks | NA NA | Incidence 2 / 30 (7%) | Incidence 14 / 33 (42%) P: 0.001 |
| Candy, 199553 | Placebo + prednisoloneRoute: Oral + OralDose: NA + 1 mg/kg every 1 d | Azathioprine + prednisoloneRoute: Oral + OralDose: 2.5 mg/kg every 1 d + 1 mg/kg every 1 d | CDAI (Remission: CDAI<175) @ 64 wks | NAYes | Incidence 14 / 33 (42%)RR: 6.36 (1.6 to 25.7) vs. main | Incidence 2 / 30 (7%) P: 0.001 |
| Arber, 1995121 | ASARoute: OralDose: 1 g every 1 d | PlaceboRoute: OralDose: NA every 24 hrs | HBI (Relapse rate: >4 increase) @ 4 wks | NAYes | Incidence 0 / 28 (0%) | Incidence 4 / 31 (14%) |
| Arber, 1995121 | ASARoute: OralDose: 1 g every 1 d | PlaceboRoute: OralDose: NA every 24 hrs | HBI (Relapse rate: >4 increase) @ 16 wks | NAYes | Incidence 1 / 28 (3%) | Incidence 7 / 31 (21%) |
| Arber, 1995121 | ASARoute: OralDose: 1 g every 1 d | PlaceboRoute: OralDose: NA every 24 hrs | HBI (Relapse rate: >4 increase) @ 52 wks | NAYes | Incidence 8 / 28 (27%) | Incidence 17 / 31 (55%) |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Relapse rate: CDAI<150 and ≥60 pt increase) @ 52 wks | NA NA | Incidence 23 / 33 (70%) | Incidence 24 / 36 (67%) |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Time to relapse) | NA NA | 124 days | 39 days |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Absolute CDAI) @ 12 wks | NA NA | B: Mean, 96 (SD, 40)F: Mean, 155 (SD, 88)F-B: 59 | B: Mean, 115 (SD, 40)F: Mean, 197 (SD, 99) F-B: 82 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Absolute CDAI) @ 52 wks | NA NA | B: Mean, 96 (SD, 40)F: Mean, 209 (SD, 106) F-B: 113 | B: Mean, 115 (SD, 40)F: Mean, 210 (SD, 119) F-B: 95 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Remission: CDAI < 150) @ 2 wks | NAYes | Incidence 7 / 67 (10%) | Incidence 7 / 66 (11%) |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Remission: CDAI < 150) @ 8 wks | NAYes | Incidence 22 / 67 (33%) | Incidence 13 / 66 (20%) P: 0.13 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 2 wks | NAYes | B: Mean, 131F: Mean, 142 F-B: 11 | B: Mean, 130F: Mean, 141 F-B: 11 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 8 wks | NAYes | B: Mean, 131F: Mean, 140 F-B: 9 | B: Mean, 130F: Mean, 141 F-B: 11 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 12 wks | NA NA | B: Mean, 185 (SD, 21)F: Mean, 170 (SD, 39) F-B: -15 | B: Mean, 181 (SD, 19)F: Mean, 154 (SD, 35) F-B: -27 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 1.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 52 wks | NA NA | B: Mean, 185 (SD, 21)F: Mean, 156 (SD, 39) F-B: -29 | B: Mean, 181 (SD, 19)F: Mean, 150 (SD, 38) F-B: -31 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Remission: CDAI < 150) @ 2 wks | NAYes | Incidence 21 / 61 (34%) | Incidence 7 / 66 (11%) |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Remission: CDAI < 150) @ 8 wks | NAYes | Incidence 31 / 61 (51%) | Incidence 13 / 66 (20%) P: <0.001 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Time to relapse) | NA NA | 178 days | 39 days |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Relapse rate: CDAI<150 and ≥60 pt increase) @ 52 wks | NA NA | Incidence 22 / 36 (61%) | Incidence 24 / 36 (67%) |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Absolute CDAI) @ 12 wks | NA NA | B: Mean, 102 (SD, 36)F: Mean, 141 (SD, 87) F-B: 39 | B: Mean, 115 (SD, 40)F: Mean, 197 (SD, 99) F-B: 82 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Absolute CDAI) @ 52 wks | NA NA | B: Mean, 102 (SD, 36)F: Mean, 182 (SD, 128) F-B: 80 | B: Mean, 115 (SD, 40)F: Mean, 210 (SD, 119) F-B: 95 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 2 wks | NAYes | B: Mean, 125F: Mean, 157 P: 0.0002 F-B: 32 | B: Mean, 130F: Mean, 141 P: 0.0002 F-B: 11 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 8 wks | NAYes | B: Mean, 125F: Mean, 166 P: <0.001 F-B: 41 | B: Mean, 130F: Mean, 141 P: <0.001 F-B: 11 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 12 wks | NA NA | B: Mean, 184 (SD, 24)F: Mean, 172 (SD, 35) F-B: -12 | B: Mean, 181 (SD, 19)F: Mean, 154 (SD, 35) F-B: -27 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 4.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 52 wks | NA NA | B: Mean, 184 (SD, 24)F: Mean, 161 (SD, 36) F-B: -23 | B: Mean, 181 (SD, 19)F: Mean, 150 (SD, 38) F-B: -31 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 7.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Remission: CDAI < 150) @ 2 wks | NAYes | Incidence 17 / 64 (27%) | Incidence 7 / 66 (11%) |
| Greenberg, 199466 | BudesonideRoute: OralDose: 7.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | CDAI (Remission: CDAI < 150) @ 8 wks | NAYes | Incidence 28 / 64 (43%) | Incidence 13 / 66 (20%) P: 0.009 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 7.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 2 wks | NAYes | B: Mean, 130F: Mean, 155 P: 0.006 F-B: 25 | B: Mean, 130F: Mean, 141 P: 0.006 F-B: 11 |
| Greenberg, 199466 | BudesonideRoute: OralDose: 7.5 mg every 12 hrs | PlaceboRoute: OralDose: NA every 12 hrs | HR QoL (IBDQ) @ 8 wks | NAYes | B: Mean, 130F: Mean, 154 P: 0.012 F-B: 24 | B: Mean, 130F: Mean, 141 P: 0.012 F-B: 11 |
| Gendre, 1993122 | Mesalamine (Pentasa)Route: OralDose: 500 mg every 6 hrs | PlaceboRoute: OralDose: NA every 6 hrs | Clinical relapses and surgical complications (Relapse rate: CDAI >250 or CDAI between 150 - 250 but over the baseline value by >50 pts with confirmation 2 wks later and surgery for acute complications) | NANR | Incidence 29 / 80 (36%) | Incidence 34 / 81 (42%) |
| Gendre, 1993122 | Mesalamine (Pentasa)Route: OralDose: 500 mg every 6 hrs | PlaceboRoute: OralDose: NA every 6 hrs | Probability of relapse or acute complication as a function of treatment and stratum (Relapse rate: CDAI > 300 or between 150 - 300 if the increase was 50 within 1 year) | NANR | Incidence 17 / 31 (55%) | Incidence 23 / 33 (71%) |
| Prantera, 1992123 | ASA (Asacol)Route: OralDose: 800 mg every 8 hrs | PlaceboRoute: OralDose: NA every 8 hrs | CDAI (Relapse rate: CDAI > 150 and 100 pt increase) @ 12 wks | NAYes | Incidence 8 / 64 (12%) | Incidence 13 / 61 (22%) |
| Prantera, 1992123 | ASA (Asacol)Route: OralDose: 800 mg every 8 hrs | PlaceboRoute: OralDose: NA every 8 hrs | CDAI (Relapse rate: CDAI > 150 and 100 pt increase) @ 52 wks | NAYes | Incidence 22 / 64 (34%) | Incidence 34 / 61 (55%) P: 0.02 |
| Brignola, 1992124 | ASA (Pentasa)Route: OralDose: 2 g every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: ileocolonic sub-group) @ 16 wks | NANo | Incidence 8 / 11 (73%) | Incidence 7 / 13 (54%) |
| Brignola, 1992124 | ASA (Pentasa)Route: OralDose: 2 g every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: CDAI >100 pt increase or >150 for more than 2 wks) @ 16 wks | NRYesNo | Incidence 11 / 21 (52%) | Incidence 13 / 22 (59%) |
| Brignola, 1992124 | ASA (Pentasa)Route: OralDose: 2 g every 24 hrs | PlaceboRoute: OralDose: NA every 24 hrs | CDAI (Relapse rate: ileal subgroup) @ 16 wks | NANo | Incidence 3 / 10 (30%) | Incidence 6 / 9 (67%) |
| Brignola, 1988112 | (6)-MethylprednisoloneRoute: UnknownDose: 0.25 mg/kg every 24 hrs | PlaceboRoute: UnknownDose: NA | CDAI (Relapse rate: Relapse after LI normalization to less than 100) | NANR | Incidence 5 / 7 (71%) | Incidence 2 / 3 (67%) |
| Brignola, 1988112 | (6)-MethylprednisoloneRoute: UnknownDose: 0.25 mg/kg every 24 hrs | PlaceboRoute: UnknownDose: NA | CDAI (Relapse rate: 100 pt increase or CDAI >150 for more than 2 wks) @ 24 wks | NANR | Incidence 1 / 9 (11%) | Incidence 7 / 9 (78%) |
| O'Donoghue, 1978100 | AzathioprineRoute: OralDose: 2 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | (Relapse rate: cumulative probability of relapse (clinically defined)) @ 24 wks | NANo | G1-G2: Mean, 0% | G1-G2: Mean, 25% P: <0.01 |
| O'Donoghue, 1978100 | AzathioprineRoute: OralDose: 2 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | (Relapse rate: cumulative probability of relapse (clinically defined)) @ 52 wks | NANo | G1-G2: Mean, 5% | G1-G2: Mean, 41% P: <0.01 |
| O'Donoghue, 1978100 | AzathioprineRoute: OralDose: 2 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | Unnamed disease activity score (Absolute score) @ 52 wks | NANo | F-B: Mean, 0.63 P: <0.05G1-G2: 1.8 | F-B: Mean, 2.46G1-G2: 1.8 |
| Bergman, 1976223 | Sulfasalazine + prednisoneRoute: Oral + OralDose: 3 g every 24 hrs + 15 mg every 24 hrs | No treatment | (Relapse rate: determined by X ray evidence) @ 132 wks | NANo | Incidence 16 / 49 (33%) | Incidence 10 / 35 (29%) |
| Bergman, 1976223 | Sulfasalazine + prednisoneRoute: Oral + OralDose: 3 g every 24 hrs + 15 mg every 24 hrs | No treatment | (Relapse rate: determined by X ray evidence) @ 52 wks | NANo | Incidence 7 / 49 (14%) | Incidence 4 / 35 (11%) |
| Bergman, 1976223 | Sulfasalazine + prednisoneRoute: Oral + OralDose: 3 g every 24 hrs + 15 mg every 24 hrs | No treatment | (Relapse rate: determined by X ray evidence of recurrence between 1 to 2 years of surgery) | NANo | Incidence 8 / 42 (19%) | Incidence 4 / 31 (13%) |
| Bergman, 1976223 | Sulfasalazine + prednisoneRoute: Oral + OralDose: 3 g every 24 hrs + 15 mg every 24 hrs | No treatment | (Relapse rate: X ray evidence of relapse between 2 to 3 years after surgery) | NANo | Incidence 1 / 34 (3%) | Incidence 2 / 27 (7%) |
| Bergman, 1976223 | Sulfasalazine + prednisoneRoute: Oral + OralDose: 3 g every 24 hrs + 15 mg every 24 hrs | No treatment | (Relapse rate: Number of recurrences during study period) @ 132 wks | NANo | Incidence 9 / 31 (29%) | Incidence 2 / 13 (15%) |
| Rosenberg, 1975104 | AzathioprineRoute: OralDose: 2 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | Reduction of steroids (average reduction of prednisolone between groups) @ 26 wks | NA NA | B: Mean, 19.1F: Mean, 3.6 P: <0.05F-B: -15.5 | B: Mean, 17.3F: Mean, 11.2F-B: -6.1 |
| Rosenberg, 1975104 | AzathioprineRoute: OralDose: 2 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | Steroid free (Taper and stopping steroids) @ 26 wks | NANR | Incidence 5 / 10 (50%) | Incidence 3 / 10 (30%) |
| Feagan, 2000105 | MethotrexateRoute: IMDose: 15 mg every 1 wks | PlaceboRoute: IMDose: NA every 1 wks | CDAI (Relapse rate: CDAI increase of 100 OR initiation of prednisone or antimetabolite) @ 4 wks | NA NA | Incidence 4 / 40 (10%) | Incidence 7 / 36 (20%) |
| Feagan, 2000105 | MethotrexateRoute: IMDose: 15 mg every 1 wks | PlaceboRoute: IMDose: NA every 1 wks | CDAI (Relapse rate: CDAI increase of 100 pts OR initiation of prednisone or antimetabolite) @ 16 wks | NA NA | Incidence 12 / 40 (29%) | Incidence 15 / 36 (42%) |
| Feagan, 2000105 | MethotrexateRoute: IMDose: 15 mg every 1 wks | PlaceboRoute: IMDose: NA every 1 wks | CDAI (Relapse rate: CDAI increase of 100 pts OR initiation of prednisone or antimetabolite) @ 40 wks | NANo | Incidence 14 / 40 (35%) | Incidence 22 / 36 (61%) P: 0.04 |
| Bresci G, 1995125 | ASARoute: UnknownDose: 2.4 g every 24 hrs | PlaceboRoute: UnknownDose: NA | CDAI (Relapse rate: CDAI ≥ 150 or 100-pt increase and LI ≥ 100) | NANo | Incidence 17 / 32 (53.1%) | Incidence 22 / 31 (70.9%) |
| Wellmann W, 1988126 | mesalamine (NR)Route: OralDose: NR | PlaceboRoute: OralDose: NA | CDAI (Relapse rate: CDAI ≥150) @ 52 wks | NANo | Incidence 10 / 31 (32%) | Incidence 14 / 35 (40%) |
| Willoughby JM, 197199 | Prednisolone + azathioprineRoute: Oral + OralDose: 60 mg every 24 hrs + 4 mg/kg every 24 hrs | Prednisolone + placeboRoute: Oral + OralDose: 60 mg every 1 d + NA every 24 hrs | Other index: (not specified) @ 24 wks | NANo | B: Mean, 10.7F: Mean, 2.3F-B: -8.4 | B: Mean, 7.8F: Mean, 8F-B: 0.2 |
| Willoughby JM, 197199 | Prednisolone + azathioprineRoute: Oral + OralDose: current + 2 mg/kg every 24 wks | Prednisolone + placeboRoute: Oral + OralDose: 60 mg every 1 d + NA every 24 hrs | Other index: (not specified) @ 24 wks | NANo | B: Mean, 3.2F: Mean, 4.4F-B: 1.2 | B: Mean, 7.8F: Mean, 8F-B: 0.2 |
| Willoughby JM, 197199 | Prednisolone + placeboRoute: Oral + OralDose: current dose + NA every 24 hrs | Prednisolone + azathioprineRoute: Oral + OralDose: 60 mg every 24 hrs + 4 mg/kg every 24 hrs | Other index: (not specified) @ 24 wks | NANo | B: Mean, 1.8F: Mean, 8.6F-B: 6.8 | B: Mean, 10.7F: Mean, 2.3F-B: -8.4 |
| Willoughby JM, 197199 | Prednisolone + azathioprineRoute: Oral + OralDose: current dose + 2 mg/kg every 24 wks | Prednisolone + placeboRoute: Oral + OralDose: current dose the patient is taking to keep him free of relapse every 24 hrs + NA every 24 hrs | Other index: (not specified) @ 24 wks | NANo | B: Mean, 3.2F: Mean, 4.4F-B: 1.2 | B: Mean, 1.8F: Mean, 8.6F-B: 6.8 |
| Singleton, 197975 | Sulfasalazine + prednisoneRoute: Oral + UnknownDose: 1g/15kg to 5g max every 1 d + 0.25 mg/kg every 1 d | Placebo + prednisoneRoute: Oral + OralDose: NA + 0.25 mg/kg every 1 d | CDAI (Remission: CDAI < 150) @ 24 wks | NANR | Incidence 3 / 16 (19%) | Incidence 2 / 18 (11%) |
| Singleton, 197975 | Sulfasalazine + prednisoneRoute: Oral + OralDose: 1g/15kg to 5g max every 1 d + 0.25 mg/kg every 1 d | Placebo + prednisoneRoute: Oral + OralDose: NA + 0.25 mg/kg every 1 d | CDAI (Remission: CDAI < 150) @ 24 wks | NANR | Incidence 3 / 13 (23%) | Incidence 2 / 18 (11%) |
| Singleton, 197975 | Placebo + prednisoneRoute: Oral + OralDose: NA + 0.25 mg/kg every 1 d | Sulfasalazine + prednisoneRoute: Oral + UnknownDose: 1g/15kg to 5g max every 1 d + 0.25 mg/kg every 1 d | CDAI (Remission: CDAI < 150) @ 24 wks | NANR | Incidence 4 / 12 (33%) | Incidence 3 / 16 (19%) |
| Singleton, 197975 | Sulfasalazine + prednisoneRoute: Oral + OralDose: 1g/15kg to 5g max every 1 d + 0.25 mg/kg every 1 d | Placebo + prednisoneRoute: Oral + OralDose: NA + 0.25 mg/kg every 1 d | CDAI (Remission: CDAI < 150) @ 24 wks | NANR | Incidence 3 / 13 (23%) | Incidence 4 / 12 (33%) |
| Summers, 197956 | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | PlaceboRoute: OralDose: NA | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 16 wks | NAYes | Incidence 8 / 58 (13%) | Incidence 11 / 101 (11%) |
| Summers, 197956 | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | PlaceboRoute: OralDose: NA | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 52 wks | NAYes | Incidence 19 / 58 (33%) | Incidence 27 / 101 (27%) |
| Summers, 197956 | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | PlaceboRoute: OralDose: NA | Perianal disease (Complete fistula closure) @ 104 wks | NANo | Incidence 1 / 6 (17%) | Incidence 2 / 7 (29%) |
| Summers, 197956 | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 16 wks | NAYes | Incidence 9 / 61 (15%) | Incidence 11 / 101 (11%) |
| Summers, 197956 | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 52 wks | NAYes | Incidence 18 / 61 (29%) | Incidence 27 / 101 (27%) |
| Summers, 197956 | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | Perianal disease (Complete fistula closure) @ 104 wks | NANo | Incidence 1 / 2 (50%) | Incidence 2 / 7 (29%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 16 wks | NAYes | Incidence 9 / 54 (16%) | Incidence 11 / 101 (11%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 52 wks | NAYes | Incidence 16 / 54 (29%) | Incidence 27 / 101 (27%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | PlaceboRoute: OralDose: NA | Perianal disease (Complete fistula closure) @ 104 wks | NANo | Incidence 0 / 3 (0%) | Incidence 2 / 7 (29%) |
| Summers, 197956 | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 16 wks | NAYes | Incidence 9 / 61 (15%) | Incidence 8 / 58 (13%) |
| Summers, 197956 | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 52 wks | NAYes | Incidence 18 / 61 (29%) | Incidence 19 / 58 (33%) |
| Summers, 197956 | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | Perianal disease (Complete fistula closure) @ 104 wks | NANo | Incidence 1 / 2 (50%) | Incidence 1 / 6 (17%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 16 wks | NAYes | Incidence 9 / 54 (16%) | Incidence 8 / 58 (13%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 52 wks | NAYes | Incidence 16 / 54 (29%) | Incidence 19 / 58 (33%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | SulfasalazineRoute: OralDose: 1/2 g/ 15 kg every 24 hrs | Perianal disease (Complete fistula closure) @ 104 wks | NANo | Incidence 0 / 3 (0%) | Incidence 1 / 6 (17%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 16 wks | NAYes | Incidence 9 / 54 (16%) | Incidence 9 / 61 (15%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | CDAI (Relapse rate: CDAI>150 and ≥100-pt increase, plus other criteria) @ 52 wks | NAYes | Incidence 16 / 54 (29%) | Incidence 18 / 61 (29%) |
| Summers, 197956 | AzathioprineRoute: OralDose: 1 mg/kg every 24 hrs | PrednisoneRoute: OralDose: 04-Jan mg/kg every 24 hrs | Perianal disease (Complete fistula closure) @ 104 wks | NANo | Incidence 0 / 3 (0%) | Incidence 1 / 2 (50%) |

Abbreviations: 95% CI = 95% Confidence Interval; 6-MP = 6-Mercaptopurine; @ = at; AE = adverse events; AP = Acute Phase; ASA = Aminosalicylates; CD = Crohn’s Disease; CDAI = Crohn’s Disease Activity Index; CDEIS = Crohn’s Disease Endoscopic Index of Severity; d= day; EQ-5D VAS = EuroQol (EQ-5D), a generic health index comprises a five-part questionnaire and a visual analogue self-rating scale; FACIT = functional assessment of chronic illness therapy; g = gram; g/kgs = gram/kilograms; h = hour; HBI = Harvey-Bradshaw Index; HR QoL= Health-related Quality of Life; hrs = hours; IBDQ = Inflammatory Bowel Disease Questionnaire; IFX= Infliximab; IM = intramuscular; IV= intravenous; IQR= inter-quartile range; ITT = intention to treat; kg = kilogram; Max. = maximum; MCS = Mental Component Score; mg = milligram; mg/d = milligram/day; mg/kg = milligram/kilogram; mg/mo = milligram/month; Min. = minimum; Mo/mos= month(s); NA = Not Applicable; NR= Not Reported; NS = not significant; OR: Odds Ratio; PCS = Physical Component Score; PGWB = Psychological General Well-Being; P = p-value; pt = point; QALY = Quality-Adjusted Life Year; rx = reaction; SC = subcutaneous; SD = standard deviation; SE= standard error; SES-CD = Simplified Endoscopic Activity Score for Crohn’s Disease; SF = Short Form; Steroid free = steroid-free remission; TNF = tumor necrosis factor; TPMT= thiopurine methyltransferase; UTD = unable to determine; VAS = visual analog scale; and wks = weeks; WPAI:CD = Work Productivity and Activity Impairment: Crohn's Disease.

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