Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
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Comparative Effectiveness of Pharmacologic Therapies for the Management of Crohn's Disease
Intervention/Population Characteristics Form

Please complete this form for RCTs and cohort studies. Submit one form per intervention group.

PLEASE IDENTIFY DRUG COMPARISONS IN THE ORDER PRESENTED HERE. For instance, if a study compares infliximab vs. infliximab + azathioprine vs. placebo, then submit 3 intervention/population forms:
1) Group 1 = placebo
2) Group 2 = infliximab
3) Group 3 = azathioprine (in first row) + infliximab (in second row)

1. Indicate the group number. **(MANDATORY QUESTION. Select one response.)**
Select an Answer

For monotherapy comparisons, please complete the first row.
For combination comparisons, please use the first row for the first drug and the second row for the second drug.

2. Intervention **(Select one response)**	3. Brand name for mesalamine only **(Select one response)**	4. Route **(Select one response)**	5. Dosing **(If prospective, randomized trial, choose dose started at randomization. Select unit and then enter a number for dose.)** Select an Answer 6. every **(Specify frequency of dosing in Q5.)** Select an Answer 7. Other dosing aspects **(Select all that apply)** ☐ Steroid taper used ☐ Dose increase permitted ☐ Dose decrease permitted ☐ Change in route during study (e.g., IV converted to oral) ☐ Induction dosing only (biologics) ☐ Induction followed by maintenance dosing (biologics) ☐ Crossover study design 8. Average cumulative dose across study **(if available)**
Select an Answer	Select an Answer	Select an Answer	
9. Intervention **(Select one response)**	10. Brand name for mesalamine only **(Select one response)**	11. Route **(Select one response)**	12. Dosing **(If prospective, randomized trial, choose dose started at randomization. Select unit and then enter a number for dose.)** Select an Answer 13. every **(Specify frequency of dosing in Q12.)** Select an Answer 14. Other dosing aspects **(Select all that apply)** ☐ Steroid taper used ☐ Dose increase permitted ☐ Dose decrease permitted ☐ Change in route during study (e.g., IV converted to oral) ☐ Induction dosing only (biologics) ☐ Induction followed by maintenance dosing (biologics) ☐ Crossover study design 15. Average cumulative dose across study **(if available)**
Select an Answer	Select an Answer	Select an Answer	

16. Comments on intervention. **(Limit 250 characters)**

17. Comments on intervention. **(Limit 250 characters)**

Population Characteristics

Please complete the baseline characteristics for this study group.

If a randomized trial, answer Q18 and skip Q19.
If a non-randomized study, skip Q18 and answer Q19.

18. If a **randomized trial,** what was the total number randomized to treatment arm? **(Enter in number from 0 to 9999999).**

19. If a **non-randomized study,** what was the total number of patients who received this treatment? **(Enter in a number from 0 to 9999999).**

For the population characteristics below, you can report either n or %.

20. **Male**

n % Gender not reported

Race

White n %

Hispanic n %

Black, African American n %

Asian n %

Other race/ethnicity n % (Specify):

Other race/ethnicity n % (Specify):

Other race/ethnicity n % (Specify):

Other race/ethnicity n % (Specify):

Race not reported

Smokers n % Definition Smoking status not reported

Age at Crohn's diagnosis (Enter number of years. If only age categories presented, enter minimum and maximum.)

Mean Median Minimum Maximum Age at diagnosis not reported

Duration of disease (Enter number of years. If only age categories presented, enter minimum and maximum.)

Mean Median Minimum Maximum Duration of disease not reported

Age at start of study (Enter number of years. If only age categories presented, enter minimum and maximum.)

Mean Median Minimum Maximum Age at study start not reported

Disease severity Metric/source used

Mild n %

Moderate n %

Mild-moderate n %

Moderate-severe n %

Severe n %

Remission/Inactive n %

Unknown/missing n %

Disease severity not reported

Disease location Metric/source used

Ileal n %

Ileo-colonic n %

Colonic n %

Perianal ☐ n ☐ % ☐

☐ Disease location not reported

Disease behavior

Inflammatory ☐ n ☐ % ☐

Stricturing ☐ n ☐ % ☐

Penetrating ☐ n ☐ % ☐

☐ Disease behavior not reported

Disease activity index

CDAI at randomization (RCTs) or study start (cohorts) ☐ Mean ☐ Median ☐ Minimum ☐ Maximum ☐

Pediatric CDAI at randomization (RCTs) or study start (cohorts) ☐ Mean ☐ Median ☐ Minimum ☐ Maximum ☐

Harvey-Bradshaw Index at randomization (RCTs) or study start (cohorts) ☐ Mean ☐ Median ☐ Minimum ☐ Maximum ☐

Other disease activity index at randomization (RCTs) or study start (cohorts) ☐ Mean ☐ Median ☐ Minimum ☐ Maximum ☐ ☐ Other index (specify): ☐

☐ Disease activity index not reported

IBDQ at randomization or study start ☐ Mean ☐ Median ☐ Minimum ☐ Maximum ☐

☐ IBDQ not reported

CRP at randomization or study start ☐ Mean ☐ Median ☐ Minimum ☐ Maximum ☐

☐ CRP not reported

Diagnosed with Crohn's Disease (for observational studies with an IBD population) ☐ n ☐ % ☐ ☐ Not reported

Medications taken by patients <u>DURING</u> the study period (Indicate which medications then record N, % of patients, if available)				
☐ Aminosalicylates	☐ n		☐ %	
☐ Antibiotics	☐ n		☐ %	
☐ Anti-TNFs	☐ n		☐ %	
☐ Corticosteroids	☐ n		☐ %	
☐ Methotrexate	☐ n		☐ %	
☐ Thiopurines	☐ n		☐ %	
☐ Immunomodulators	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	

Medications taken by patients <u>BEFORE</u> the study period (Indicate which medications then record N, % of patients, if available)				
☐ Aminosalicylates	☐ n		☐ %	
☐ Antibiotics	☐ n		☐ %	
☐ Anti-TNFs	☐ n		☐ %	
☐ Corticosteroids	☐ n		☐ %	
☐ Methotrexate	☐ n		☐ %	
☐ Thiopurines	☐ n		☐ %	
☐ Immunomodulators	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	
☐ Other medication (specify):	☐ n		☐ %	

Medications taken by patients <u>BEFORE</u> the study period or during the run-in period to <u>INDUCE REMISSION</u> (Indicate which medications then record N, % of patients, if

available)

Aminosalicylates	n		%	
Antibiotics	n		%	
Anti-TNFs	n		%	
Corticosteroids	n		%	
Methotrexate	n		%	
Thiopurines	n		%	
Immunomodulators	n		%	
Other medication (specify):	n		%	
Other medication (specify):	n		%	
Other medication (specify):	n		%	
Other medication (specify):	n		%	

127. Comments on population characteristics. **(Limit 250 characters)**

128. Comments on population characteristics. **(Limit 250 characters)**

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