Table 42. Patient characteristics–haloperidol versus risperidone

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Apiquian et al. 2008**45 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Outpatient  ***Country:*** Mexico  ***Financial support:*** NR  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 4 wks | ***Main inclusion criteria:*** Pts (17–50 yrs) Dx with Sz (DSM–IV), with acute psychosis; PANSS (positive) >16, score of at least 4 on at least two subscale items  ***Main exclusion criteria:*** Other primary psychiatric or physical illnesses, current substance abuse or dependence, high risk for suicide or violence; or severe akathisia | ***G1:***  ***Age (mean±SD):*** 28.50±7.20  ***Males (n(%)):*** 13/15 (86.7%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 77.8±10.5  ***G2:***  ***Age (mean±SD):*** 28.50±7.20  ***Males (n(%)):*** 12/17 (70.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 85.1±11.3 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2mg/d  ***Intervals:*** nightly dosing  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 1mg/d  ***Intervals:*** nightly dosing |
| **Blin et al. 1996**52 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Inpatient  ***Country:*** France  ***Financial support:*** NR  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 4 wks | ***Main inclusion criteria:*** Pts (18–50 yrs) with Sz (DSM–III–R) with acute exacerbation and symptoms of anxiety (Psychotic Anxiety Scale score at least 34)  ***Main exclusion criteria:*** Schizo–affective disorders; severe somatic disorders; abnormal lab results; Hx of drug/alcohol abuse; pregnant/ lactating women; pts receiving long–acting antipsychotic agents during last 4 wks or short–acting antipsychotics during last 48 hrs or other treatments that might interfere with the trial medication or pt's emotional state | ***G1:***  ***Age (mean±SD):*** 33.90±NR  ***Males (n(%)):*** 11/20 (86.7%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 66.3±15.8  CGI-BP (mean±SD): 4.5±0.8  PANSS (mean±SD): 119±21.8  ***G2:***  ***Age (mean±SD):*** 34.80±NR  ***Males (n(%)):*** 14/21 (66.7%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 70.1±12.2  CGI-BP (mean±SD): 4.6±0.8  PANSS (mean±SD): 124.4±19.7 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 4–12mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4–12mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Borison et al. 1992**53 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Multicenter  ***Setting:*** NR  ***Country:*** USA  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** NA  ***Run-in phase performed:*** yes (1 wk)  ***Followup period:*** 6 wks | ***Main inclusion criteria:*** Pts with Sz (DSM–III–R); BPRS score at least 30, with 2 or more positive symptom items (unusual thought content, hallucinations, conceptual disorganization, suspiciousness); Baseline CGI of moderate or greater  ***Main exclusion criteria:*** Clinically significant medical/neurological problems or concomitant psychiatric diagnoses, substance abuse or dependence | ***G1:***  ***Age (mean±SD):*** 37.00±6.00  ***Males (n(%)):*** 12/12 (100%)  ***Ethnicity:*** Caucasian 6/12 (50%)  ***BL symptom scores:*** BPRS (mean±SD): 50±6  ***G2:***  ***Age (mean±SD):*** 43.00±9.00  ***Males (n(%)):*** 12/12 (100%)  ***Ethnicity:*** Caucasian 6/12 (50%)  ***BL symptom scores:*** BPRS (mean±SD): 52±5 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 4–20mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–10mg/d  ***Intervals:*** NR |
| **Cavallaro et al. 2001**59 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Inpatient  ***Country:*** Italy  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** NA  ***Run-in phase performed:*** yes (≤1 wk)  ***Followup period:*** 6 wks | ***Main inclusion criteria:*** Pts with subchronic Sz (DSM–II–R); able to consent; not treated with neuroleptics in past wk. or depot APs in past mo.  ***Main exclusion criteria:*** Other major morbidity; substance/alcohol abuse; known hypersensitivity to included Tx; IQ <80. | ***G1:***  ***Age (mean±SD):*** 23.20±2.30  ***Males (n(%)):*** 10/14 (71.4%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 25.40±5.10  ***Males (n(%)):*** 12/15 (80%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2.5–10mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2.5–10mg/d  ***Intervals:*** BID |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Ceskova et al. 1993**60 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** ICD–9  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Inpatient  ***Country:*** Czech Republic  ***Financial support:*** NR  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Pts with Sz (ICD–9)  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 37.00±6.00  ***Males (n(%)):*** 12/12 (100%)  ***Ethnicity:*** Caucasian 6/12 (50%)  ***BL symptom scores:*** BPRS (mean±SD): 50±6  ***G2:***  ***Age (mean±SD):*** 43.00±9.00  ***Males (n(%)):*** 12/12 (100%)  ***Ethnicity:*** Caucasian 6/12 (50%)  ***BL symptom scores:*** BPRS (mean±SD): 52±5 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2–20mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–20mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Chouinard et al. 1993**61 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Multicenter(n = 6)  ***Setting:*** Inpatient  ***Country:*** Canada  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** yes (2 d to 2 wks)  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Pts (18–65 yrs) with Dx of Sz; PANSS score 60–120; hospitalized for first 3 wks of the study; no depot neuroleptics for one treatment cycle  ***Main exclusion criteria:*** Women: pregnant/lactating/without adequate contraception; mental disorder other than Sz; epilepsy; Hx of psychoactive substance/alcohol abuse; significant abnormal lab or ECG results | ***G1:***  ***Age (mean±SD):*** 37.00±10.00  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 55.7±14.5  PANSS (mean±SD): 95.4±23.5  ***G2:***  ***Age (mean±SD):*** 37.00±10.00  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 53.6±14.9  PANSS (mean±SD): 93.9±22.7  ***G3:***  ***Age (mean±SD):*** 37.00±10.00  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 57.5±13.1  PANSS (mean±SD): 98±22.6  ***G4:***  ***Age (mean±SD):*** 37.00±10.00  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 50.8±12.7  PANSS (mean±SD): 89.9±19.2  ***G5:***  ***Age (mean±SD):*** 37.00±10.00  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 54.5±12.6  PANSS (mean±SD): 94.3±21.3 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 20mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2mg/d  ***Intervals:*** BID  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 6mg/d  ***Intervals:*** BID  ***G4:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 10mg/d  ***Intervals:*** BID  ***G5:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 16mg/d  ***Intervals:*** BID |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Citrome et al. 2001**62 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** 1996 to 2000  ***Number of centers:*** Multicenter(n = 4)  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Multiple sources (Janssen, Eli Lilly, Novartis, Merck)  ***Washout period performed:*** NA  ***Run-in phase performed:*** yes (1 wk)  ***Followup period:*** 14 wks | ***Main inclusion criteria:*** Pts with Sz (18–60 yrs); Hx of suboptimal treatment response; PANSS minimum score of 60; persistent positive symptoms after six wks with one or more conventional antipsychotics (600 mg chlorpromazine equivalent or more); poor level of functioning over past two yrs  ***Main exclusion criteria:*** Hx of not responding to clozapine, risperidone, or olanzapine; Hx of intolerance to any of the study drugs; receipt of depot AP during last 30 d | ***G1:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 31/37 (83.8%)  ***Ethnicity:*** Caucasian 11/37 (29.7%)  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 34/40 (85%)  ***Ethnicity:*** Caucasian 12/40 (30%)  ***BL symptom scores:*** NR  ***G3:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 33/39 (84.6%)  ***Ethnicity:*** Caucasian 12/39 (30.8%)  ***BL symptom scores:*** NR  ***G4:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 35/41 (85.4%)  ***Ethnicity:*** Caucasian 13/41 (31.7%)  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 10–30mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Clozapine  ***Dosage:*** 200–800mg/d  ***Intervals:*** NR  ***G3:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 10–40mg/d  ***Intervals:*** NR  ***G4:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4–16mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Claus et al. 1992**64 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Multicenter(n = 5)  ***Setting:*** Inpatient  ***Country:*** Belgium  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** yes (1 wk)  ***Run-in phase performed:*** yes (2 wks)  ***Followup period:*** 12 wks | ***Main inclusion criteria:*** Pts (18–67 yrs) with chronic Sz (DSM–III–R); hospitalized <10 yrs  ***Main exclusion criteria:*** Pts with clinically relevant organic diseases; pregnant/lactating women or in their reproductive phase without adequate contraceptive measures | ***G1:***  ***Age (mean±SD):*** 39.00±NR  ***Males (n(%)):*** 13/21 (61.9%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 79.8±21.12  ***G2:***  ***Age (mean±SD):*** 37.40±NR  ***Males (n(%)):*** 15/21 (71.4%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 91.1±18.79 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 1–10mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 1–10mg/d  ***Intervals:*** BID |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Crespo-Facorro et al. 2006**71 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** Feb–01 to Feb–05  ***Number of centers:*** Single center  ***Setting:*** Mixed  ***Country:*** Spain  ***Financial support:*** Multiple sources (NR)  ***Washout period performed:*** yes (3–5d)  ***Run-in phase performed:*** no  ***Followup period:*** 6 wks | ***Main inclusion criteria:*** Pts (15–60 yrs) with Sz (DSM–IV); no AP within 6 wks; SAPS of moderate severity  ***Main exclusion criteria:*** Mental retardation; drug dependence | ***G1:***  ***Age (mean±SD):*** 28.30±8.70  ***Males (n(%)):*** 36/56 (64.3%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 62.4±10.9  YMRS (mean±SD): 9.3±4.3  ***G2:***  ***Age (mean±SD):*** 27.50±6.90  ***Males (n(%)):*** 33/55 (60%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 59.9±12.1  YMRS (mean±SD): 9.2±4.7  ***G3:***  ***Age (mean±SD):*** 26.10±7.60  ***Males (n(%)):*** 38/61 (62.3%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 56.8±10.3  YMRS (mean±SD): 8.8±4.8 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 3–9mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 5–20mg/d  ***Intervals:*** NR  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 3–6mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Csernansky et al. 2002**72 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** May–96 to Sep–98  ***Number of centers:*** Multicenter(n = 40)  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** yes (≤1 wks)  ***Run-in phase performed:*** no  ***Followup period:*** 12 mo | ***Main inclusion criteria:*** Pts (18–65 yrs) with of Sz or schizoaffective disorder (DSM–IV) requiring hospitalization; clinically stable within last 30 d  ***Main exclusion criteria:*** Another current DSM–IV Axis I Dx, an Axis II Dx of borderline personality disorder or antisocial personality disorder; substance dependence/abuse; clinically significant or unstable medical illness; current treatment with clozapine; Hx of refractoriness to AP; Tx with depot neuroleptic injections within one treatment cycle; allergic to either risperidone or haloperidol; pregnant/nursing women | ***G1:***  ***Age (mean±SD):*** 40.10±10.40  ***Males (n(%)):*** 128/188 (68.1%)  ***Ethnicity:*** Caucasian 93/188 (49.5%)  ***BL symptom scores:*** PANSS (mean±SD): 67.3±17.4  ***G2:***  ***Age (mean±SD):*** 40.30±10.60  ***Males (n(%)):*** 127/77 (71.8%)  ***Ethnicity:*** Caucasian 81/177 (45.8%)  ***BL symptom scores:*** PANSS (mean±SD): 65±15.9 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 5–20mg/d  ***Intervals:*** once/d  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–8mg/d  ***Intervals:*** once/d |
| **de Sena et al. 2003**77 | ***Study design***: NonRCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** Mar–95 to Nov–97  ***Number of centers:*** Single center  ***Setting:*** Unclear  ***Country:*** Brazil  ***Financial support:*** Industry (Janssen–Cilag)  ***Washout period performed:*** yes (3–7d)  ***Run-in phase performed:*** no  ***Followup period:*** 12 mo | ***Main inclusion criteria:*** Pts (15–40 yrs) with Sz (DSM–III–R)  ***Main exclusion criteria:*** Long hospitalization (≥12 months); other Axis I disorders; drug dependence; significant neurological or organic disorders; Pts difficult to follow–up; participation in a trial during 4 wks prior to the study; use of depot neuroleptics with one treatment cycle before the start of the study | ***G1:***  ***Age (mean±SD):*** 27.40±NR  ***Males (n(%)):*** 13/13 (100%)  ***Ethnicity:*** Caucasian 2/13 (15.4%)  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 27.90±NR  ***Males (n(%)):*** 20/20 (100%)  ***Ethnicity:*** Caucasian 4/20 (20%)  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 5–17mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 1–6mg/d  ***Intervals:*** BID |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Emsley et al. 1999**81 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Multicenter(n = 61)  ***Setting:*** Inpatient  ***Country:*** Australia, Belgium, Canada, France, Germany, Great Britain, Korea, The Netherlands, South Africa, Sweden  ***Financial support:*** NR  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 6 wks | ***Main inclusion criteria:*** Pts (15–45 yrs) with Sz or schizophreniform disorder (DSM–III–R) without prior Tx; had psychotic symptoms requiring Tx; had received a maximum of 3 d of ED Tx for this disorder; had no clinically relevant neurological, ECG or lab test abnormalities; informed consent  ***Main exclusion criteria:*** Pregnant/lactating women or of reproductive age not using adequate contraception; other mental illness; psychoactive substance abuse; previous depot antipsychotic Tx; clinically significant organic disease; participated in clinical trials of investigational drugs within 4 wks | ***G1:***  ***Age (mean±SD):*** 24.00±NR  ***Males (n(%)):*** 54/84 (64.3%)  ***Ethnicity:*** Caucasian 62/84 (73.8%)  ***BL symptom scores:*** BPRS (mean±SD): 89.6±20.16  CGI-S (mean±SD): 51.5±8.62  ***G2:***  ***Age (mean±SD):*** 26.00±NR  ***Males (n(%)):*** 68/99 (68.7%)  ***Ethnicity:*** Caucasian 62/99 (62.6%)  ***BL symptom scores:*** BPRS (mean±SD): 89.1±18.81  CGI-S (mean±SD): 51.1±10.89 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2–10mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–10mg/d  ***Intervals:*** BID |
| **Fakra et al. 2008**82 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–IV–TR  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Inpatient  ***Country:*** France  ***Financial support:*** Multiple sources (Janssen)  ***Washout period performed:*** yes (1 wk)  ***Run-in phase performed:*** no  ***Followup period:*** 50 wks | ***Main inclusion criteria:*** Pts (18–55 yrs) with Sz (DSM–IV)  ***Main exclusion criteria:*** Hx of alcohol/drug abuse; comorbidity with depressive or anxiety disorders; chronic medical illness other than Sz; facial TD; taking depot antipsychotics | ***G1:***  ***Age (mean±SD):*** 37.80±11.40  ***Males (n(%)):*** 12/14 (85.7%)  ***Ethnicity:*** Caucasian 13/14 (92.9%)  ***BL symptom scores:*** PANSS (mean±SD): 75.21±8.65  ***G2:***  ***Age (mean±SD):*** 33.90±9.50  ***Males (n(%)):*** 7/11 (63.6%)  ***Ethnicity:*** Caucasian 10/11 (90.9%)  ***BL symptom scores:***  PANSS (mean±SD): 76.1±15.46 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** NR  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** NR  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Heck et al. 2000**85 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** 1993 to 1995  ***Number of centers:*** Multicenter(n = 12)  ***Setting:*** Mixed  ***Country:*** Netherlands  ***Financial support:*** Industry (Janssen–Cilag)  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** NR | ***Main inclusion criteria:*** Pts (18–70 yrs) with Sz (DSM–III–R); clinically stable on current meds; score of at least 5 on ESRS or use anti-Parkinson medication  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 44.50±NR  ***Males (n(%)):*** 12/22 (54.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 40.00±NR  ***Males (n(%)):*** 13/25 (52%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 3–24mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–16mg/d  ***Intervals:*** BID |
| **Kee et al. 1998**99 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Multiple sources (Janssen)  ***Washout period performed:*** yes (<1 wks)  ***Run-in phase performed:*** yes (3 wks)  ***Followup period:*** NR | ***Main inclusion criteria:*** Sz disorder based on the Structured Clinical Interview for DSM–III–R, treatment–resistant  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 37.67±8.37  ***Males (n(%)):*** 7/9 (77.8%)  ***Ethnicity:*** Caucasian 5/9 (55.6%)  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 35.00±9.72  ***Males (n(%)):*** 5/9 (55.6%)  ***Ethnicity:*** Caucasian 5/9 (55.6%)  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 15mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 6mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Keefe et al. 2003**100 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** NR  ***Country:*** USA  ***Financial support:*** Multiple sources (Janssen)  ***Washout period performed:*** yes (<1 wks)  ***Run-in phase performed:*** no  ***Followup period:*** NR | ***Main inclusion criteria:*** Dx with Sz by DSM–IV criteria were assessed; Pts were included in the study only if their age ranged between 18–55  ***Main exclusion criteria:*** If English was not their first language, not having any of the target symptoms (autonoetic agnosia: thought insertion, voices arguing, voices commenting, made feelings, made acts, or made impulses) | ***G1:***  ***Age (mean±SD):*** 33.90±11.70  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 36.6±6  ***G2:***  ***Age (mean±SD):*** 33.90±11.70  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 36.6±6  ***G3:***  ***Age (mean±SD):*** NR  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2.5–10.0mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 2.5–10.0mg/d  ***Intervals:*** NR  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2.0–8.0mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Keefe et al. 2006**101 | ***Study design:*** RCT  ***Registration #:*** F1D–MC–HGGN  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** July 1999–Nov 2000 to July 1999–Nov 2001  ***Number of centers:*** Multicenter(n = 39)  ***Setting:*** Mixed  ***Country:*** USA, Canada  ***Financial support:*** Industry (Eli Lilly)  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 52 wks | ***Main inclusion criteria:*** 18–55yrs; schizophrenia or schizoaffective disorder; PANSS score ≥ 4 on at least 2 positive items; BPRS score ≥18; English speaking; have a level of understanding sufficient to agree to all tests and examinations; had illness duration of at least 2 yrs from first hospitalization and/or diagnosis/treatment; female pts of childbearing potential must have been using a medically accepted means of contraception.  ***Main exclusion criteria:*** Previous participation in present study, participated in a clinical trial of another investigational drug within 1 mo.; participated in a study within the past 3 mo. that included the neurocognitive battery; significant neurological disorder, head injury with loss of consciousness; serious illness such that death was anticipated within 1 yr or intensive care hospitalization was anticipated within 6 mo, QTc interval greater than 450 ms, uncorrected hypo– or hyperthyroidism, current agranulocytosis, female patients who were either pregnant or nursing, allergic reaction to study medication, DSM–IV substance dependence) within past 2 mo, Tx with depot antipsychotics, reversible MAO inhibitor within 2 wks, or clozapine or ECT within 1 mo. | ***G1:***  ***Age (mean±SD):*** 39.80±8.32  ***Males (n(%)):*** 69/97 (71.1%)  ***Ethnicity:*** Caucasian 51/97 (52.6%)  ***BL symptom scores:*** MADRS (mean±SD): 14.4±10.2  PANSS (mean±SD): 82.7±14.1  ***G2:***  ***Age (mean±SD):*** 38.40±7.90  ***Males (n(%)):*** 115/159 (72.3%)  ***Ethnicity:*** Caucasian 95/159 (59.8%)  ***BL symptom scores:*** MADRS (mean±SD): 13.2±8.7  PANSS (mean±SD): 82.6±13.1  ***G3:***  ***Age (mean±SD):*** 39.50±8.25  ***Males (n(%)):*** 111/158 (70.3%)  ***Ethnicity:*** Caucasian 101/158 (63.9%)  ***BL symptom scores:*** MADRS (mean±SD): 14.1±9.3  PANSS (mean±SD): 84.1±14.7 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2–19mg/d  ***G2:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 5–20mg/d  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–10mg/d |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Kim et al. 2010**102 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** NR  ***Study period:*** NR  ***Number of centers:*** *Two–center*  ***Setting:*** Outpatient  ***Country:*** South Korea  ***Financial support:*** Other (Choi Shine  ***Hae 2008–2009)***  ***Washout period performed:*** yes (>4wks)  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Pts with Sz, aged 20–64 yrs, attending outpatient departments at two sites in Korea; all participants were smokers; they were clinically stable, with no changes in their antipsychotic medication prescriptions.  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 42.50±8.70  ***Males (n(%)):*** 25/35 (71.4%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 37.10±4.80  ***Males (n(%)):*** 23/31 (74.2%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G3:***  ***Age (mean±SD):*** 41.80±11.40  ***Males (n(%)):*** 23/32 (71.9%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G4:***  ***Age (mean±SD):*** 39.90±12.80  ***Males (n(%)):*** 28/41 (68.3%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 15.9+/-7.1mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Aripiprazole  ***Dosage:*** 21.7+/-5.5 mg/d  ***Intervals:*** NR  ***G3:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 15.9+/-4.3mg/d  ***Intervals:*** NR  ***G4:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4.8+/-2.9mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Lee et al. 2007**107 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** NR  ***Number of centers:*** *Two–center*  ***Setting:*** Inpatient  ***Country:*** Taiwan  ***Financial support:*** Government  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Sz Pt identified on the basis of ICD–9  ***Main exclusion criteria***: no previous Hx of other functional psychosis, neurological illnesses/insults, substance abuse within the past 2 yrs; Hx of substance dependence, electroconvulsive therapy within the past 6 months, or any other significant current medical conditions | ***G1:***  ***Age (mean±SD):*** 27.20±10.40  ***Males (n(%)):*** 10/10 (100%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 89.5±15.2  ***G2:***  ***Age (mean±SD):*** 25.90±7.25  ***Males (n(%)):*** 10/10 (100%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 94.2±9.8 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 7.6+/-2.6mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4.1+/-0.8mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Lim et al. 2010**151 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Bipolar disorder and Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** Dec 2005 to Sept 2006  ***Number of centers:*** *Single center*  ***Setting:*** Inpatient  ***Country:*** South Korea  ***Financial support:*** Industry (Janssen)  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 24 h | ***Main inclusion criteria:*** Age 18–65 yrs; manifestation  of acute psychotic agitation in the ED or inpatient ward; Sz or schizoaffective disorder, bipolar I disorder with or without psychotic features, delusional  disorders, or psychotic disorder not otherwise specified; symptom score of ≥ 14 on the 5–item acute agitation cluster derived from the PANSS–EC; score of ≥ 3 on the  CGI–S  ***Main exclusion criteria:*** Neurological disorders or severe medical diseases; alcohol or other psychoactive substance abusers; treated with any antipsychotics or benzodiazepines within 6 h of enrollment; Hx of neuroleptic malignant syndrome or hypersensitivity to trial medications; treated with a depot antipsychotic within 1 Tx cycle of enrollment; eligible women were tested for pregnancy; pregnant and lactating women | ***G1:***  ***Age (mean±SD):*** 34.70±10.20  ***Males (n(%)):*** 32/62 (51.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 32.30±9.80  ***Males (n(%)):*** 34/62 (54.8%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 5–15mg  ***Intervals:*** could repeat every 2 hr (max 15mg/24 hr)  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–6mg  ***Intervals:*** could repeat every 2 hr (max 6mg/24 hr) |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Liu et al. 2000**111 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** *Single center*  ***Setting:*** Mixed  ***Country:*** Taiwan  ***Financial support:*** NR  ***Washout period performed:*** yes (1 wk)  ***Run-in phase performed:*** no  ***Followup period:*** 12 wk | ***Main inclusion criteria:*** Prominent clinical symptoms as revealed by a total score of > 65 on the PANSS  ***Main exclusion criteria:*** Patients with a previous history of physical illness or substance abuse that cast the Dx in doubt | ***G1:***  ***Age (mean±SD):*** 35.10±13.00  ***Males (n(%)):*** 6/19 (31.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 86.1±14.9  ***G2:***  ***Age (mean±SD):*** 32.70±8.40  ***Males (n(%)):*** 9/19 (47.4%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 76±16.1 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** NR  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** NR  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Marder et al. 1994**114 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Multicenter(n = 20)  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Industry (Janssen–Ortho)  ***Washout period performed:*** yes (1 wk)  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Dx of Sz otherwise physically healthy; PANSS total score ≥60, ≤120  ***Main exclusion criteria:*** Schizoaffective disorder; women with childbearing potential | ***G1:***  ***Age (mean±SD):*** 38.00±10.00  ***Males (n(%)):*** 60/66 (90.9%)  ***Ethnicity:*** Caucasian 41/66 (62.1%)  ***BL symptom scores:*** BPRS (mean±SD): 54.6±10.7  PANSS (mean±SD): 92.9±17.4  ***G2:***  ***Age (mean±SD):*** 39.30±10.90  ***Males (n(%)):*** 54/63 (85.7%)  ***Ethnicity:*** Caucasian 41/63 (65.1%)  ***BL symptom scores:*** BPRS (mean±SD): 51.5±10.2  PANSS (mean±SD): 87.4±17.6  ***G3:***  ***Age (mean±SD):*** 10.00±11.10  ***Males (n(%)):*** 55/64 (85.9%)  ***Ethnicity:*** Caucasian 42/64 (65.6%)  ***BL symptom scores:*** BPRS (mean±SD): 54.1±11.7  PANSS (mean±SD): 93.8±19.1  ***G4:***  ***Age (mean±SD):*** 36.20±9.80  ***Males (n(%)):*** 61/65 (93.9%)  ***Ethnicity:*** Caucasian 42/65 (64.6%)  ***BL symptom scores:*** BPRS (mean±SD): 54±11.8  PANSS (mean±SD): 92.5±19.4  ***G5:***  ***Age (mean±SD):*** 36.50±10.40  ***Males (n(%)):*** 53/64 (82.8%)  ***Ethnicity:*** Caucasian 38/64 (59.4%)  ***BL symptom scores:*** BPRS (mean±SD): 54.2±10.5  PANSS (mean±SD): 93.8±17.2 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 20mg/d  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2mg/d  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 6mg/d  ***G4:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 10mg/d  ***G5:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 16mg/d |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Marder et al. 2003**113 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  Study period: NR  ***Number of centers:*** Multicenter(n = 3)  ***Setting:*** Outpatient  ***Country:*** USA  ***Financial support:*** Multiple sources (Janssen Research  ***Foundation)***  ***Washout period performed:*** NA  ***Run-in phase performed:*** yes (2 wks)  ***Followup period:*** 2 yrs | ***Main inclusion criteria:*** All subjects were 18–60 yrs of age; had at least two documented episodes of acute schizophrenic illness or at least 2 yrs of continuing psychotic symptoms; had been outpatients for at least 1 month; and were considered candidates for maintenance therapy with an antipsychotic  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 43.30±8.40  ***Males (n(%)):*** 29/30 (96.7%)  ***Ethnicity:*** Caucasian 14/30 (46.7%)  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 43.70±9.20  ***Males (n(%)):*** 29/33 (87.9%)  ***Ethnicity:*** Caucasian 14/33 (42.4%)  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2mg TID.  for the first week and then 6mg h.s.  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2mg TID.  for the first week and then 6mg h.s. |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **McCue et al. 2006**73 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** Jan 2004 to Feb 2005  ***Number of centers:*** *Single center*  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** NR  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 3 wks | ***Main inclusion criteria:*** Pts (≥18 yrs) newly admitted for Sz, schizoaffective disorder or schizophreniform disorder  ***Main exclusion criteria:*** Pregnant/lactating women; medical condition in which pharmacotherapy would prove a significant clinical risk; Hx of response or lack of response to AP; Dx of BP, major depressive disorder, substance–induced psychotic disorder | ***G1:***  ***Age (mean±SD):*** 35.70±10.80  ***Males (n(%)):*** 42/57 (73.7%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 42±11.3  ***G2:***  ***Age (mean±SD):*** 40.50±12.60  ***Males (n(%)):*** 27/53 (51%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD):  41.3±10.2  ***G3:***  ***Age (mean±SD):*** 39.00±11.00  ***Males (n(%)):*** 32/50 (64%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 43.6±10.4  ***G4:***  ***Age (mean±SD):*** 33.80±10.10  ***Males (n(%)):*** 37/52 (71.2%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 41.1±11  ***G5:***  ***Age (mean±SD):*** 38.60±12.90  ***Males (n(%)):*** 34/57 (59.7%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 42.3±9  ***G6:***  ***Age (mean±SD):*** 38.30±11.90  ***Males (n(%)):*** 26/50 (52%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 43.4±11 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 4–30mg  ***G2:***  ***Classification:*** SGA  ***Drug:*** Aripiprazole  ***Dosage:*** 10–45mg  ***G3:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 5–40 mg  ***G4:***  ***Classification:*** SGA  ***Drug:*** Quetiapine  ***Dosage:*** 50–1200 mg  ***G5:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–9 mg  ***G6:***  ***Classification:*** SGA  ***Drug:*** Ziprasidone  ***Dosage:***40–240 mg |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Min et al. 1993**117 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** *Single center*  ***Setting:*** Mixed  ***Country:*** Korea  ***Financial support:*** NR  ***Washout period performed:*** yes (1 wk)  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Chronic Sz; age 18–65 yrs.; PANSS score >60 and <120; normal laboratory and ECG tests; hospitalized d 6–14 if possible  ***Main exclusion criteria:*** Other mental disorder; clinically significant co–morbidity; epilepsy; Hx of alcohol–or drug abuse within 12–month; included in other investigational drug trial within 4 wks; women not on adequate contraception, pregnant or lactating | ***G1:***  ***Age (mean±SD):*** 34.10±NR  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 48.8±14.8  PANSS (mean±SD): 88.2±28.2  ***G2:***  ***Age (mean±SD):*** 34.10±NR  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD):  53.4±18.4  PANSS (mean±SD): 92±30 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2.5–5mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2.5–5mg/d  ***Intervals:*** BID |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Moller et al. 2008**118 | ***Study design:*** RCT  ***Registration #:*** NCTOOI59081  ***Study population:*** Schizophrenia  ***DSM Classification:*** ICD–10 F20  ***Study period***: Nov 2000 to May 2004  ***Number of centers:*** Multicenter(n = 13)  ***Setting:*** Inpatient  ***Country:*** Germany  ***Financial support:*** Multiple sources (Janssen–Cilag)  ***Washout period performed:*** yes (1 wk)  ***Run-in phase performed:*** no  ***Followup period:*** 2 yrs | ***Main inclusion criteria:*** Having recovered from a first illness episode with a diagnosis according to ICD–10 F20, whereas first episode was pragmatically defined as the first inpatient treatment of psychotic symptoms; age between 18–55 yrs; having either participated in the acute Tx study or being suited for lateral entry; being sufficiently able in German language; having given consent after extensive information about the various phases and ramifications of the 2–yr study  ***Main exclusion criteria:*** Pregnancy; insufficient response to pretreatment with risperidone or haloperidol; other contraindications for risperidone or haloperidol; mental retardation; organic brain disease; substance abuse; Hx of suicidal behavior; severe physical disease; participation in other trials | ***G1:***  ***Age (mean±SD):*** 30.70±10.00  ***Males (n(%)):*** 80/146 (54.8%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 80.8±24.8  YMRS (mean±SD): 5.5±5.5  ***G2:***  ***Age (mean±SD):*** 29.50±9.50  ***Males (n(%)):*** 92/143 (64.3%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 77.3±23  YMRS (mean±SD):  5±5.2 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2–8mg/d  ***Intervals:*** Once daily  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–8mg/d  ***Intervals:*** Once daily |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Peuskens et al. 1995**120 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Multicenter(n = 110)  ***Setting:*** Inpatient  ***Country:*** International (15 countries)  ***Financial support:*** NR  ***Washout period performed:*** yes (3–7d)  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Dx of chronic Sz disorder according to DSM–III–R with a total score between 60–120 on the PANSS  ***Main exclusion criteria:*** Clinically significant organic or neurological disorders, epilepsy, psychiatric disorders other than chronic schizophrenia, a history of alcohol or drug abuse in the previous 12 months, or had participated in trials of investigational drugs in the preceding 4 wks; pregnant or lactating women and those of reproductive age without adequate contraception | ***G1:***  ***Age (mean±SD):*** 38.10±NR  ***Males (n(%)):*** 150/226 (66.4%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 48.1±10.22  PANSS (mean±SD): 90.1±17.86  ***G2:***  ***Age (mean±SD):*** 38.40±NR  ***Males (n(%)):*** 166/229 (72.5%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD):  48.9±10.59  PANSS (mean±SD): 32.9±7.88  ***G3:***  ***Age (mean±SD):*** 38.10±NR  ***Males (n(%)):*** 152/227 (67%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 48.6±10.09  PANSS (mean±SD): 89.6±17.48  ***G4:***  ***Age (mean±SD):*** 37.60±NR  ***Males (n(%)):*** 144/230 (62.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 48.1±10.92  PANSS (mean±SD): 89.2±18.81  ***G5:***  ***Age (mean±SD):*** 37.90±NR  ***Males (n(%)):*** 142/226 (62.8%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 49.1±10.07  PANSS (mean±SD): 90.5±18.04  ***G6:***  ***Age (mean±SD):*** 38.50±  ***Males (n(%)):*** 140/224 (62.5%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 49.5±10.63  PANSS (mean±SD): 89.8±17.96 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 10mg/d  ***Intervals:*** 2 times per d distributed evenly  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 1mg/d  ***Intervals:*** 2 times per d distributed evenly  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4mg/d  ***Intervals:*** 2 times per d distributed evenly  ***G4:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 8mg/d  ***Intervals:*** 2 times per d distributed evenly  ***G5:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 12mg/d  ***Intervals:*** 2 times per d distributed evenly  ***G6:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:***16mg/d  ***Intervals:*** 2 times per d distributed evenly |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Purdon et al. 2000**124 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** NR  ***Number of centers:*** Multicenter(n = 19)  ***Setting:*** Outpatient  ***Country:*** Canada  ***Financial support:*** Industry (Eli Lilly)  ***Washout period performed:*** yes (2–9d)  ***Run-in phase performed:*** yes (1 month)  ***Followup period:*** 54 wks | ***Main inclusion criteria:*** Men and women aged 18–65 yrs who were within 5 yrs of their first exposure to neuroleptic treatment and had symptom severity at least in the mild range  ***Main exclusion criteria:*** Pregnant or lactating, had prior medical histories of central nervous system disease or severe head injury, or if they had active serious illness or substance abuse disorders in the previous 30 d | ***G1:***  ***Age (mean±SD):*** 28.83±6.52  ***Males (n(%)):*** 15/23 (65.2%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 33.17±7.88  ***G2:***  ***Age (mean±SD):*** 26.01±5.76  ***Males (n(%)):*** 17/21 (81%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 32.9±7.88  ***G3:***  ***Age (mean±SD):*** 31.77±11.24  ***Males (n(%)):*** 14/21 (66.7%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 30.29±6.73 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 5–20mg/d  ***G2:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 5–20mg/d  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–6mg/d |
| **Remillard et al. 2008**125 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** Multicenter  ***Setting:*** Outpatient  ***Country:*** Canada, France  ***Financial support:*** Industry (Janssen–Ortho)  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 12 mo | ***Main inclusion criteria:*** Dx of Sz with DSM–III–R  ***Main exclusion criteria:*** no Hx of drug or alcohol abuse or neurological disease | ***G1:***  ***Age (mean±SD):*** 44.10±9.40  ***Males (n(%)):*** 11/14 (78.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 40.60±9.90  ***Males (n(%)):*** 11/14 (78.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 2–40mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–6mg/d  ***Intervals:*** BID |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Schooler et al. 2005**132 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period***: Nov 1996 to Jan 2000  ***Number of centers:*** Multicenter(n = 12)  ***Setting:*** Outpatient  ***Country:*** Australia, Austria, Canada, Finland, France, Germany, Israel, Netherlands, New Zealand, South Africa, UK, USA  ***Financial support:*** Industry (Johnson and Johnson)  ***Washout period performed:*** yes (3–7d)  ***Run-in phase performed:*** no  ***Followup period:*** 2 yrs | ***Main inclusion criteria:*** Age 16–45yrs; Sz, schizophreniform disorder, or schizoaffective disorder ≤ 1 yr; no more than two psychiatric hospitalizations for psychosis; <12 wks of cumulative exposure to APs; required AP Tx upon enrollment  ***Main exclusion criteria:*** Meeting DSM–IV criteria for another axis I diagnosis, including substance dependence or abuse; needing another nonantipsychotic psychotropic medication at enrollment; having a serious or unstable medical illness | ***G1:***  ***Age (mean±SD):*** 25.70±6.87  ***Males (n(%)):*** 200/277 (72.2%)  ***Ethnicity:*** Caucasian 208/277 (75.1%)  ***BL symptom scores:*** PANSS (mean±SD): 81.1±20.1  ***G2:***  ***Age (mean±SD):*** 25.20±6.84  ***Males (n(%)):*** 196/278 (70.5%)  ***Ethnicity:*** Caucasian 205/277 (73.7%)  ***BL symptom scores:*** PANSS (mean±SD): 83.7±20.22 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 1–8mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 1–8mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Sergi et al. 2007**134 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** NR  ***Number of centers:*** Multicenter  ***Setting:*** Outpatient  ***Country:*** USA  ***Financial support:*** Multiple sources (Janssen and Forest, and Eli Lilly)  ***Washout period performed:*** no(No washout period was used)  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Sz patients DSM–IV age between 18–60 yrs old, competence to provide informed consent, no identifiable neurological conditions or mental retardation, and no alcohol or substance dependence in the last 6 months  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 50.00±5.80  ***Males (n(%)):*** 13/13 (100%)  ***Ethnicity:*** Caucasian 4/13 (30.8%)  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 48.20±7.70  ***Males (n(%)):*** 24/28 (85.7%)  ***Ethnicity:*** Caucasian 16/28 (57.1%)  ***BL symptom scores:*** NR  ***G3:***  ***Age (mean±SD):*** 49.20±6.70  ***Males (n(%)):*** 28/32 (87.5%)  ***Ethnicity:*** Caucasian 9/32 (28.1%)  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 8mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 15mg/d  ***Intervals:*** NR  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4mg/d  ***Intervals:*** NR |
| **Shrivastava et al. 2000**135 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** NR  ***Number of centers:*** Single center  ***Setting:*** Inpatient  ***Country:*** India  ***Financial support:*** NR  ***Washout period performed:*** NA  ***Run-in phase performed:*** yes (2–4 wks)  ***Followup period:*** 12 mo | ***Main inclusion criteria:*** Admitted for acute exacerbation of Sz  ***Main exclusion criteria:*** NR | ***G1:***  ***Age (mean±SD):*** 31.80±4.80  ***Males (n(%)):*** 30/50 (60%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 89.1±4.8  ***G2:***  ***Age (mean±SD):*** 36.20±3.50  ***Males (n(%)):*** 29/50 (58%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 91.9±5.9 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 5–15mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Tamrakar et al. 2006**139 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** ICD–10  ***Study period:*** Jan 2002 to Jun 2002  ***Number of centers:*** *Single center*  ***Setting:*** NR  ***Country:*** Nepal  ***Financial support:*** NR  ***Washout period performed:*** yes (1 wk for oral; 4 wks for depot)  ***Run-in phase performed:*** no  ***Followup period:*** 6 wks | ***Main inclusion criteria:*** Pts between 18–45 yrs of age Dx with Sz according to ICD–10  ***Main exclusion criteria:*** Pts with comorbid psychiatric and medical illnesses | ***G1:***  ***Age (mean±SD):*** 28.67±4.16  ***Males (n(%)):*** 10/18 (55.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 88.56±13.35  ***G2:***  ***Age (mean±SD):*** 27.28±4.38  ***Males (n(%)):*** 12/18 (66.7%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 88.17±15.7 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 10–20mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4–6mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Volakva et al. 2002**145 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** June 1996 to NR  ***Number of centers:*** Multicenter(n = 4)  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Multiple sources (Janssen, Eli Lilly, Novartis, Merck)  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 14 wks | ***Main inclusion criteria:***Dx of DSM–IV chronic Sz or schizoaffective disorder and suboptimal response to previous treatment, which was defined by two criteria that needed to be present (persistent positive symptoms after at least 6 contiguous wks of Tx presently or documented in the past, with one or more typical antipsychotics at doses =600 mg/d in chlorpromazine equivalents, and poor level of functioning over the past 2 yrs, defined by the lack of competitive employment or enrollment in an academic or vocational program and not having age–expected interpersonal relations with someone outside the biological family of origin with whom ongoing regular contacts were maintained), a baseline total score =60 on the PANSS  ***Main exclusion criteria:*** Hx of nonresponse to clozapine, risperidone, or olanzapine, defined as an unambiguous lack of improvement despite a contiguous adequate trial of risperidone or olanzapine for at least 6 wks, or clozapine for at least 14 wks, a history of clozapine, olanzapine, risperidone, or haloperidol intolerance as well as those who received a depot antipsychotic within 30 d before randomization | ***G1:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 133/167 (79.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 90.4±11.6  ***G2:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 133/167 (79.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 97.6±17.1  ***G3:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 133/167 (79.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 91±13.5  ***G4:***  ***Age (mean±SD):*** 40.80±9.20  ***Males (n(%)):*** 133/167 (79.6%)  ***Ethnicity:*** NR  ***BL symptom scores:*** BPRS (mean±SD): 89.5±13.8 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 10–30mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Clozapine  ***Dosage:*** 200–800mg/d  ***Intervals:*** BID  ***G3:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 10–40mg/d  ***Intervals:*** BID  ***G4:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4–16mg/d  ***Intervals:*** BID |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Wirshing et al. 1999**146 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** *Two–center*  ***Setting:*** Inpatient  ***Country:*** USA  ***Financial support:*** Multiple sources (Janssen)  ***Washout period performed:*** yes (3–7d)  ***Run-in phase performed:*** yes (3 wks)  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Age 18–60 yrs: Dx of Sz; considered Tx resistant; able to take oral medication; BPRS ≥ 45; minimum score of 4 on two BPRS items: conceptual disorganization, suspiciousness, hallucinations, or unusual thought content; CGI ≥ 4. Meet treatment refractory requirement.  ***Main exclusion criteria:*** Had experienced a period of good functioning within 5 yrs; clinically significant neurologic disease; seizure disorder; Hx of head injury; physical, cognitive, or language impairment that would affect ratings; substance abuse within 6 mo.; previous trial of risperidone sufficient to determine clinical response; Tx with investigational drugs or clozapine within 4 wks; depot neuroleptics within 8 wks; behavior that posed significant danger to self or others; significant clinical improvement between the initial screening and the start of the study. | ***G1:***  ***Age (mean±SD):*** 40.00±8.20  ***Males (n(%)):*** 29/33 (87.9%)  ***Ethnicity:*** Caucasian 16/33 (48.5%)  ***BL symptom scores:*** BPRS (mean±SD): 70.8±14.6  ***G2:***  ***Age (mean±SD):*** 41.00±9.40  ***Males (n(%)):*** 26/34 (76.5%)  ***Ethnicity:*** Caucasian 20/34 (58.8%)  ***BL symptom scores:*** BPRS (mean±SD): 66.8±14.3 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 15mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 6mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Wynn et al. 2007**148 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** NR  ***Number of centers:*** Multicenter(n = 3)  ***Setting:*** Unclear  ***Country:*** USA  ***Financial support:*** Multiple sources (Eli Lilly, Janssen, F.P. Medications)  ***Washout period performed:*** NA  ***Run-in phase performed:*** no  ***Followup period:*** 8 wks | ***Main inclusion criteria:*** Age 18–60 yrs.; Dx with Sz, schizoaffective disorder (bipolar and depressive subtypes); competent to provide informed consent.  ***Main exclusion criteria:*** Mental retardation, identifiable neurological conditions; alcohol and substance dependence in the last six months | ***G1:***  ***Age (mean±SD):*** 50.30±6.20  ***Males (n(%)):*** 11/11 (100%)  ***Ethnicity:*** Caucasian 4/11 (36.4%)  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** 49.80±7.20  ***Males (n(%)):*** 17/21 (81%)  ***Ethnicity:*** Caucasian 14/21 (66.7%)  ***BL symptom scores:*** NR  ***G3:***  ***Age (mean±SD):*** 46.80±8.30  ***Males (n(%)):*** 15/19 (79%)  ***Ethnicity:*** Caucasian 6/19 (31.6%)  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 8mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Olanzapine  ***Dosage:*** 15mg/d  ***Intervals:*** NR  ***G3:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 4mg/d  ***Intervals:*** NR |

Table 42. Patient characteristics–haloperidol versus risperidone (continued)

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Yen et al. 2004**149 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** *Single center*  ***Setting:*** NR  ***Country:*** Taiwan  ***Financial support:*** Government  ***Washout period performed:*** yes (7 d from oral neuroleptics; 4 wks for depot preparations)  ***Run-in phase performed:*** no  ***Followup period:*** 12 wks | ***Main inclusion criteria:*** Age 18–65 yrs.; Dx with Sz; total PANSS score >60  ***Main exclusion criteria:*** Suffering from psychoses other than Sz, with early childhood brain damage, unable to comply with the medication, with a severe illness (including hematological, hepatic, or cardiovascular disease; pulmonary embolism; alcoholism or addiction), and pregnant or lactating women. | ***G1:***  ***Age (mean±SD):*** 34.00±6.61  ***Males (n(%)):*** 11/20 (55%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 90.2±16.4  ***G2:***  ***Age (mean±SD):*** 32.90±10.30  ***Males (n(%)):*** 15/21 (71.4%)  ***Ethnicity:*** NR  ***BL symptom scores:*** PANSS (mean±SD): 90.5±16.5 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 4–20mg/d  ***Intervals:*** Once daily  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 2–12mg/d  ***Intervals:*** Once daily |
| **Zhang et al. 2001**150 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM–III–R  ***Study period:*** NR  ***Number of centers:*** *Single center*  ***Setting:*** Inpatient  ***Country:*** China  ***Financial support:*** NR  ***Washout period performed:*** NA  ***Run-in phase performed:*** yes (2 wks)  ***Followup period:*** 12 wks | ***Main inclusion criteria:*** Inpatients in Beijing Huilongguan Hospital; DSM–III–R criteria for schizophrenia; Pts Tx with three conventional neuroleptics for at least 3 months at full dose; duration of illness for at least 5 yrs; age between 25–60 yrs, with a CGI scale ratings of a score of 4 or higher  ***Main exclusion criteria:*** Significant medical illness or were actively abusing alcohol or illegal drugs | ***G1:***  ***Age (mean±SD):*** 43.70±8.10  ***Males (n(%)):*** 30/37 (81.1%)  ***Ethnicity:*** Caucasian 0/37 (0%)  ***BL symptom scores:*** PANSS (mean±SD): 79.3±21.7  ***G2:***  ***Age (mean±SD):*** 43.80±6.40  ***Males (n(%)):*** 30/41 (73.2%)  ***Ethnicity:*** Caucasian 0/41 (0%)  ***BL symptom scores:*** PANSS (mean±SD): 82.4±22.4 | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 6mg/d  ***Intervals:*** NR  ***G2:***  ***Classification:*** SGA  ***Drug:*** Risperidone  ***Dosage:*** 20mg/d  ***Intervals:*** NR |

AP = antipsychotic; BID  = Twice daily; BL = baseline; BP  = Bipolar Disorder; BPRS = Brief Psychiatric Rating Scale; CGI = Clinical Global Impressions; d = day; DSM = Diagnostic and Statistical Manual of Mental Disorders; DX = diagnosis; ECG  = Electrocardiography; ; ED  = Emergency Department; FGA = first-generation antipsychotic; Hx = history; MADRS  = Montgomery-Asberg Depression Rating Scale; MAO  = Monoamine oxidase; mg = milligram; n = number; NA = not applicable; NR = not reported; PANSS  = Positive and Negative Syndrome Scale; QTc  = Corrected QT interval; RCT = randomized controlled trial; SAPS  = Scale for the Assessment of Positive Symptoms; SD = standard deviation; SGA = second-generation antipsychotic; Sz = schizophrenia; TD  = Tardive dyskinesia; Tx = treatment; wk = week; YMRS = Young Mania Rating Scale; yr = year