Table 38. Patient characteristics–haloperidol versus asenapine

| **Author, Year** | **Study Characteristics** | **Inclusion and Exclusion Criteria** | **Population** | **Interventions** |
| --- | --- | --- | --- | --- |
| **Kane et al. 2010**97 | ***Study design:*** RCT  ***Registration #:*** NR  ***Study population:*** Schizophrenia  ***DSM Classification:*** DSM IV  ***Study period:*** Jun 2005 to Sep 2006  ***Number of centers:*** Multicenter(n = 43)  ***Setting:*** Mixed  ***Country:*** USA, Canada, Russia, India, Romania, Croatia  ***Financial support:*** Industry (Schering–Plough)  ***Washout period performed:*** yes (1–3d)  ***Run-in phase performed:*** no  ***Followup period:*** 6 wks | ***Main inclusion criteria:*** At least 18 Yrs; DSM–IV Sz with acute exacerbation of psychotic symptoms; PANSS score ≥60; scores ≥ 4 on 2 of 5 predefined PANSS pos subscale items (delusions, conceptual disorganization, hallucinatory behavior, grandiosity, and suspiciousness/persecution); CGI–S score ≥4.  ***Main exclusion criteria:*** Clinically significant medical condition or abnormal laboratory or physical examination findings; Dx of residual–type Sz, schizoaffective disorder, or coexisting psychiatric disorder coded on Axis I; current or past substance abuse; 20% or higher decrease in PANSS total score from screening to baseline; known allergy or sensitivity to haloperidol; imminent risk of self–harm or harm to others; and previous participation in an asenapine trial. | ***G1:***  ***Age (mean±SD):*** NR  ***Males (n(%)):***NR  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G2:***  ***Age (mean±SD):*** NR  ***Males (n(%)):*** NR  ***Ethnicity:*** NR  ***BL symptom scores:*** NR  ***G3:***  ***Age (mean±SD):*** NR  ***Males (n(%)):***NR  ***Ethnicity:*** NR  ***BL symptom scores:*** NR | ***G1:***  ***Classification:*** FGA  ***Drug:*** Haloperidol  ***Dosage:*** 4mg/d  ***Intervals:*** BID  ***G2:***  ***Classification:*** SGA  ***Drug:*** Asenapine  ***Dosage:*** 5mg/d  ***Intervals:*** BID  ***G3:***  ***Classification:*** SGA  ***Drug:*** Asenapine  ***Dosage:*** 10mg/d  ***Intervals:*** BID |

AP = antipsychotic; BID = Twice daily; BL = baseline; BPRS = Brief Psychiatric Rating Scale; CGI = Clinical Global Impressions; d = day; DSM = Diagnostic and Statistical Manual of Mental Disorders; FGA = first-generation antipsychotic; mg = milligram; n = number; NR = not reported; PANSS = Positive and Negative Syndrome Scale; RCT = randomized controlled trial; SD = standard deviation; SGA = second-generation antipsychotic; Sz = schizophrenia; Tx = treatment; wk = week; yr = year