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Data supplement

Table DS1 Demographic and baseline characteristics

Variable	Regimen A[a] (*n*=125)	Regimen B[b] (*n*=132)
Ages, years		
Mean (s.d.)	15.6 (1.25)	15.6 (1.32)
Range	(13–17)	(13–17)
Gender, %		
Female	60 (48)	52 (39)
Male	65 (52)	80 (61)
Ethnicity,[c] *n* (%)		
Black or African American	17 (14)	20 (15)
Mixed	2 (2)	0
White	104 (85)	111 (85)
Weight, kg: mean (s.d.)	60.6 (10.47)	63.9 (11.52)
Weight, kg: *n* (%)		
<50	18 (14)	11 (8)
⩾50	107 (86)	121 (92)
Body mass index, kg/m^2: mean (s.d.)	21.4 (3.20)	22.2 (3.39)
Tanner stage, *n* (%)		
2	1 (1)	2 (2)
3	17 (14)	19 (14)
4	50 (40)	51 (39)
5	57 (46)	60 (45)
Diagnosis, *n* (%)		
Catatonic	4 (3)	3 (2)
Disorganised	13 (10)	6 (5)
Paranoid	83 (66)	92 (70)
Residual	0	7 (5)
Undifferentiated	25 (20)	24 (18)
Children's Global Assessment Scale score, mean (s.d.)	40.6 (13.59)	41.9 (12.18)
Baseline Clinical Global Impression Scale – Severity,[d] mean (s.d.)	5.1 (0.83)	4.9 (0.84)
Age at first onset of psychiatric symptoms, years: mean (s.d.)	14.0 (2.13)	13.7 (2.49)
Age, start of first psychiatric treatment,[e] years: mean (s.d.)	15.0 (1.55)	15.0 (1.73)
Age at diagnosis, years: mean (s.d.)	15.3 (1.30)	15.3 (1.61)
Time since first onset of psychiatric symptoms, years: mean (s.d.)	1.7 (1.75)	1.9 (2.19)

a. Weight ⩾50 kg: risperidone 1.5–6.0 mg/day; weight <50 kg: 0.03–0.12 mg/kg/day.
b. Weight ⩾50 kg: risperidone 0.15–0.6 mg/day; weight <50 kg: 0.003–0.012 mg/kg/day.
c. Regimen A (*n*=123), regimen B (*n*=131).
d. Regimen A (*n*=124), regimen B (*n*=131).
e. Regimen A (*n*=124), regimen B (*n*=130).

Table DS2 Secondary efficacy assessments – mean changes from baseline to end-point[a]

Variable	Regimen A[b] (*n*=124)	Regimen B[c] (*n*=131)
PANSS positive symptoms		
Baseline, mean (s.d.)	26.5 (5.16)	26.6 (5.16)
Change from baseline, mean (s.d.)	−7.6 (7.11)	−4.8 (6.26)
Between group comparison, change from baseline, *P*-value[d]	<0.001	
Between group difference (95% CI)[e]	−2.88 (−4.43 to −1.34)	
Effect size[f]	0.46	
PANSS negative symptoms		
Baseline, mean (s.d.)	24.6 (7.54)	23.3 (6.61)
Change from baseline, mean (s.d.)	−5.5 (7.88)	−2.5 (6.43)
Between group comparison, change from baseline, *P*-value[d]	0.003	
Between group difference (95% CI)[e]	−2.40 (−3.98 to −0.82)	
Effect size[f]	0.38	
Disorganised thoughts		
Baseline, mean (s.d.)	22.4 (5.79)	21.5 (5.59)
Change from baseline, mean (s.d.)	−5.0 (5.67)	−2.5 (4.95)
Between group comparison, change from baseline, *P*-value[d]	<0.001	
Between group difference (95% CI)[e]	−2.31 (−3.57 to −1.05)	
Effect size[f]	0.46	
Uncontrolled hostility/excitement		
Baseline, mean (s.d.)	11.4 (3.95)	10.6 (3.56)
Change from baseline, mean (s.d.)	−2.9 (4.63)	−1.0 (3.62)
Between group comparison, change from baseline, *P*-value[d]	0.002	
Between group difference (95% CI)[e]	−1.46 (−2.38 to −0.55)	
Effect size[f]	0.40	
Anxiety/depression		
Baseline, mean (s.d.)	11.5 (3.58)	11.3 (3.31)
Change from baseline, mean (s.d.)	−2.6 (4.33)	−1.7 (3.58)
Between group comparison, change from baseline, *P*-value[d]	0.058	
Between group difference (95% CI)[e]	−0.79 (−1.61 to 0.03)	
Effect size[f]	0.24	
Clinical Global Impression – Severity		
Baseline, mean (s.d.)	5.1 (0.83)	4.9 (0.84)
Change from baseline, mean (s.d.)	−1.4 (1.23)	−0.9 (1.22)
Between group comparison, change from baseline, *P*-value[d]	<0.001	
Between group difference (95% CI)[e]	−0.59 (−0.89 to −0.29)	
Effect size[f]	0.48	
Clinical Global Impression – Improvement		
End-point, mean (s.d.)	2.6 (1.28)	3.2 (1.41)
Between group comparison, *P*-value[d]	<0.001	
Between group difference (95% CI)[e]	−0.58 (−0.91 to −0.24)	
Effect size[f]	0.43	

PANSS, Positive and Negative Syndrome Scale.
a. Data from two participants excluded from analysis because of irregularities noted in a quality assurance audit; exclusion had no effect on the efficacy conclusions.
b. Risperidone 1.5–6.0 mg/day.
c. Risperidone 0.15–0.60 mg/day.
d. Test for no difference between treatment groups from ANCOVA model with factors for treatment group and country and baseline value as covariate (baseline value was not included in the model for the analysis of Clinical Global Impression–Improvement scores).
e. Difference (regimen A – regimen B) in least squares means and 95% CI from ANCOVA model.
f. Difference in least squares means divided by the square root of the mean square error from the ANCOVA model.

Table DS3 Incidence[a] of treatment-emergent adverse events: event with ⩾5% incidence in either group

Adverse event	Regimen A[b] (*n*=125), *n* (%)	Regimen B[c] (*n*=132), *n* (%)
Total number of patients with adverse events	93 (74.4)	86 (65.2)
Central and peripheral nervous system disorders	56 (44.8)	39 (29.5)
Hypertonia	18 (14.4)	6 (4.5)
Headache	13 (10.4)	23 (17.4)
Tremor	13 (10.4)	4 (3.0)
Hyperkinesia	11 (8.8)	2 (1.5)
Dyskinesia	7 (5.6)	2 (1.5)
Psychiatric disorders	54 (43.2)	38 (28.8)
Somnolence	33 (26.4)	11 (8.3)
Anxiety	7 (5.6)	2 (1.5)
Insomnia	6 (4.8)	12 (9.1)
Agitation	5 (4.0)	11 (8.3)
Gastrointestinal system disorders	32 (25.6)	27 (20.5)
Abdominal pain	9 (7.2)	8 (6.1)
Vomiting	9 (7.2)	5 (3.8)
Metabolic and nutritional disorders	24 (19.2)	13 (9.8)
Weight increase	22 (17.6)	7 (5.3)
Body as a whole, general disorders	20 (16.0)	26 (19.7)
Pain	7 (5.6)	8 (6.1)
Injury	3 (2.4)	7 (5.3)
Respiratory system disorders	18 (14.4)	15 (11.4)
Upper respiratory tract infection	8 (6.4)	5 (3.8)
Heart rate and rhythm disorders	10 (8.0)	7 (5.3)
Tachycardia	7 (5.6)	4 (3.0)

a. Incidence is based on the number of patients experiencing at least one adverse event, not the number of events.
b. Risperidone 1.5–6.0 mg/day.
c. Risperidone 0.15–0.60 mg/day.