TOPLINE RESULTS			
Report date:	**29 August 2001**	**Tracking number:**	GBSR-01-072
Trial number:	RIS-INT-41	**Clinical Phase:**	III
Title:	The long-term safety and efficacy of Risperdal® in conduct disorder in mild, moderate and borderline mentally retarded children aged 5 to 14 years.		
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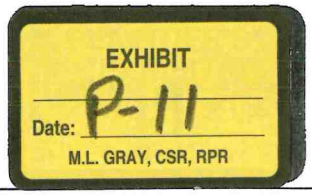
Trial Design

- Multicenter, open-label, uncontrolled trial, 0.02 to 0.06 mg/kg/day of oral Risperdal® in conduct and other disruptive behaviour disorders in children with mild, moderate or borderline intellectual impairment (defined as an IQ of 35 to 84) aged 5 to 14 years inclusive.
- Treatment regimen: Subjects would undergo a 1 week placebo run-in period in order to identify placebo responders. The trial medication was administered once daily.
- Treatment duration: 1 year.
- Trial duration: 24 months.
- Planned sample size: The planed sample size was approximately 500 subjects. This number was based on the regulatory requirements for long-term safety and efficacy data.
- An interim analysis of 319 subjects who entered the study before 31 July 1999 was performed for Year 2000 CDMR submission.

Statistical hypothesis for primary objective: This trial was a long-term safety trial, there was no primary statistical hypothesis.



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The results in this summary have been verified by the Global Biometrics and Submission Team statisticians and programmers. Nevertheless, it is possible that these results may differ slightly from what will appear in the final Clinical Trial Report (CTR). Results presented in the CTR will be the final, fully validated results of this trial. All information about the trial results is considered confidential and no further discussions or dissemination of results occur with anyone else until approval is given from the head of Clinical R&D and Regulatory Affairs, Worldwide.

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Conclusion:
Safety: The safety profile in this trial was, in general, consistent with those in other pediatric conduct disorder trials. Risperidone was well tolerated. No unexpected adverse events were reported. The type of adverse events was similar to those seen during short-term treatment with risperidone.
Efficacy: The primary efficacy parameter was the change from baseline to endpoint of conduct problem subscale of the N-CBRF. The mean change was -15.8 (SE=0.53) at endpoint, which was a highly statistically significant improvement. Improvement was particularly marked during the first 4 weeks of treatment, with scores remaining stable theafter.

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RESULTS

1. MAIN FEATURES OF THE TRIAL

In addition to new patients enrolled to this open label trial, 23 patients who completed RIS-CAN-19 (an 8 week double blind placebo controlled trial) entered this trial. Out of the 23 patients, 10 were randomized to treatment with risperidone and 13 to placebo. In tables throughout this document, "Risperidone" group shows subjects newly entered in RIS-INT-41, while "RIS (CAN-19)" refers to subjects from RIS-CAN-19. The "All Subjects" category combines these two groups.

Trial disposition and subject characteristics	Risperidone	RIS (CAN-19)	All Subjects
# of subjects screened	566	23	589
# of subjects with risperidone	**481**	**23**	**504**
Sex (M/F)	400/81	19/4	419/85
Age, years:			
Mean (SE)	9.7 (0.11)	8.8 (0.45)	9.7 (0.11)
Median (min-max)	10 (4-14)	9 (5-12)	10 (4-14)
Race			
White	407 (84.6%)	18 (78.3%)	425 (84.3%)
Black	32 (6.7%)	5 (21.7%)	37 (7.3%)
Hispanic	6 (1.2%)	0 (0.0%)	6 (1.2%)
Oriental	2 (0.4%)	0 (0.0%)	2 (0.4%)
Other	34 (7.1%)	0 (0.0%)	34 (6.7%)
IQ-rating:			
Mean (SE)	64 (0.62)	68.1 (2.17)	64.2 (0.6)
Median (min-max)	66 (35-84)	70 (49-83)	66 (35-84)
DSM-IV AXIS I			
ADHD	10 (2.1%)	0 (0.0%)	10 (2.0%)
ADHD+BD NOS	49 (10.2%)	2 (8.7%)	51 (10.1%)
ADHD+CD	96 (20.0%)	9 (39.1%)	105 (20.8%)
ADHD+ODD	90 (18.7%)	5 (21.7%)	95 (18.8%)
BD NOS	32 (6.7%)	1 (4.3%)	33 (6.5%)
CD	118 (24.5%)	2 (8.7%)	120 (23.8%)
ODD	86 (17.9%)	4 (17.4%)	90 (17.9%)
DSM-IV AXIS II			
Borderline mental retardation	178 (37.1%)	11 (47.8%)	189 (37.6%)
Mild mental retardation	206 (42.9%)	11 (47.8%)	217 (43.1%)
Moderate mental retardation	96 (20.0%)	1 (4.3%)	97 (19.3%)
# of subjects with post-baseline NCBRF (ITT)	473	23	496

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Trial termination reasons for all subjects who received risperidone treatment are summarized below

Trial termination reasons	Risperidone	RIS (CAN-19)	All Subjects
Total subjects with risperidone treatment	481	23	504
Completed	351 (73.0%)	16 (69.6%)	367 (72.8%)
Discontinued	130 (27.0%)	7 (30.4%)	137 (27.2%)
- D/C'd due to adverse event	42 (8.7%)	1 (4.3%)	43 (8.5%)
- D/C'd due to insufficient response	16 (3.3%)	2 (8.7%)	18 (3.6%)
- D/C'd due to other reasons	7 (1.5%)	1 (4.3%)	8 (1.6%)
- D/C'd due to asymptomatic / cured	0 (0.0%)	1 (4.3%)	1 (0.2%)
- D/C'd due to ineligible to continue the trial	2 (0.4%)	0 (0.0%)	2 (0.4%)
- D/C'd due to lost to follow-up	25 (5.2%)	1 (4.3%)	26 (5.2%)
- D/C'd due to non-compliant	16 (3.3%)	1 (4.3%)	17 (3.4%)
- D/C'd due to withdrew consent	22 (4.6%)	0 (0.0%)	22 (4.4%)

The mean dose of trial medication (mg/kg per day) is summarized below.

Mean dose (days on drug only)	Risperidone	RIS (CAN-19)	All Subjects
Number assessed Distribution, N (%)	479	23	502
0 - < 0.01	6 (1.3%)	0 (0.0%)	6 (1.2%)
0.01 - < 0.02	33 (6.9%)	1 (4.3%)	34 (6.8%)
0.02 - < 0.03	74 (15.4%)	5 (21.7%)	79 (15.7%)
0.03 - < 0.04	130 (27.1%)	4 (17.4%)	134 (26.7%)
0.04 - < 0.05	90 (18.8%)	7 (30.4%)	97 (19.3%)
0.05 - < 0.06	139 (29.0%)	6 (26.1%)	145 (28.9%)
>= 0.06	7 (1.5%)	0 (0.0%)	7 (1.4%)
Mean (SE)	0.04 (0.0006)	0.041 (0.0028)	0.04 (0.0006)
Median (min, max)	0.04 (0.01, 0.08)	0.043 (0.02, 0.06)	0.04 (0.01, 0.08)

The duration of risperidone treatment is summarized below.

Extent of exposure (days)	Risperidone	RIS (CAN-19)	All Subjects
Treatment duration, days Number assessed	481	23	504
Mean (SE)	306.41 (5.192)	326.09 (14.703)	307.31 (5.001)
Median (min, max)	358 (1, 505)	338 (46, 399)	358 (1, 505)

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2. EFFICACY

All efficacy analyses are on the subjects who used study medication and had at least one post-baseline assessment for the N-CBRF (ITT subjects).

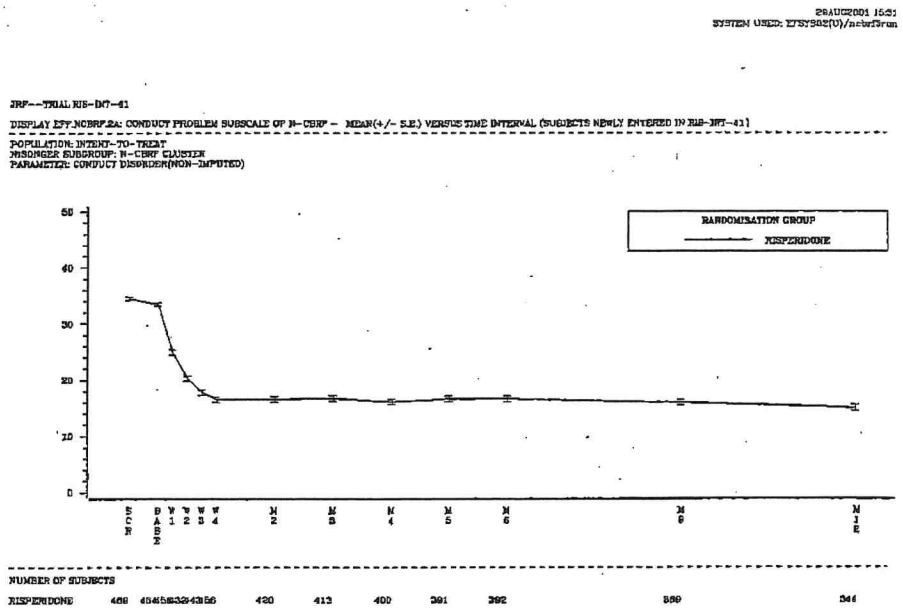
2.1. Primary efficacy variable – Change in conduct problem subscale of NCBRF scores from baseline to endpoint

The conduct problem subscale of N-CBRF scores was statistically significantly improved in all subjects from open label baseline at endpoint.

Conduct Problem Subscale of NCBRF (Non-imputed)

	Risperidone			RIS (CAN-19)			All Subjects		
	N	Mean (SE)	Mean change (SE)	n	Mean (SE)	Mean change (SE)	n	Mean (SE)	Mean change (SE)
Baseline	464	33.50 (0.308)		23	20.96 (2.651)		487	32.91 (0.340)	
Month 12	344	15.06 (0.555)	-17.9 (0.554)	19	16.89 (2.689)	-0.95 (3.337)	363	15.16 (0.544)	-17.0 (0.588)
Endpoint	473	16.92 (0.503)	-16.5 (0.512)	23	19.09 (2.654)	-1.87 (2.876)	496	17.02 (0.495)	-15.8 (0.525)

Means (+/-SE) of conduct problem subscale of N-CBRF scores over time for the subjects who newly entered RIS-INT-41 is plotted below.



2.2. Major secondary efficacy variables

2.2.1. Aberrant Behaviour Checklist (ABC) (New patients)

Total ABC (Non-imputed)	Risperidone (n=473)			
			Change from open label baseline	
	N	Mean ± SE	Mean ± SE	95% CI
Baseline	426	65.6 ± 1.17		
Month 12	319	32.8 ± 1.36	-33.7 ± 1.50	(-36.7 ; -30.8)
Endpoint	433	37.2 ± 1.28	-29.6 ± 1.37	(-32.3 ; -26.9)

2.2.2. Clinical Global Impression (CGI) (New patients)

	Risperidone (n=473)					
	Baseline (n=467)		Month 12 (n=348)		Endpoint (n=461)	
CGI rating	n	(%)	n	(%)	n	(%)
Not ill	0	(0.0)	40	(11.5)	46	(10.0)
Very mild	1	(0.2)	111	(31.9)	121	(26.2)
Mild	19	(4.1)	111	(31.9)	138	(29.9)
Moderate	105	(22.5)	61	(17.5)	99	(21.5)
Marked	169	(36.2)	20	(5.7)	38	(8.2)
Severe	142	(30.4)	4	(1.1)	16	(3.5)
Extremely severe	31	(6.6)	1	(0.3)	3	(0.7)

Overall 305 (66.2%) subjects showed no, very mild or mild symptoms at endpoint (57, 12.4% marked to extremely severe) compared to 20 (4.3%) with very mild or mild symptoms at baseline (342, 73.2% marked to extremely severe).

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3. SAFETY

Safety analyses are on the all subjects who received risperidone treatment.

3.1. Common adverse events

3.1.1. AEs >= 10% OF THE SUBJECTS

Adverse events during risperidone treatment period are summarized below. Only AEs reported for ≥ 10% of the subjects are shown.

	Risperidone	RIS(CAN-19)	All Subjects
Total no. subj. with treatment	**481**	**23**	**504**
Total no. subj. with adverse event	**439 (91.3)**	**23 (100)**	**462 (91.7)**
Respiratory system disorders	*249 (51.8)*	*15 (65.2)*	*264 (52.4)*
Rhinitis	128 (26.6)	9 (39.1)	137 (27.2)
Coughing	62 (12.9)	5 (21.7)	67 (13.3)
Pharyngitis	70 (14.6)	4 (17.4)	74 (14.7)
Upper resp tract infection	81 (16.8)	2 (8.7)	83 (16.5)
Psychiatric disorders	*231 (48.0)*	*14 (60.9)*	*245 (48.6)*
Somnolence	138 (28.7)	11 (47.8)	149 (29.6)
Appetite increased	53 (11.0)	0 (0.0)	53 (10.5)
Gastro-intestinal system disorders	*179 (37.2)*	*12 (52.2)*	*191 (37.9)*
Vomiting	55 (11.4)	5 (21.7)	60 (11.9)
Body as a whole - general disorders	*229 (47.6)*	*11 (47.8)*	*240 (47.6)*
Injury	50 (10.4)	4 (17.4)	54 (10.7)
Fever	59 (12.3)	3 (13.0)	62 (12.3)
Fatigue	68 (14.1)	1 (4.3)	69 (13.7)
Centr & periph nervous system disorders	*212 (44.1)*	*11 (47.8)*	*223 (44.2)*
Headache	103 (21.4)	7 (30.4)	110 (21.8)
Endocrine disorders	*74 (15.4)*	*7 (30.4)*	*81 (16.1)*
Hyperprolactinaemia	51 (10.6)	5 (21.7)	56 (11.1)
Metabolic and nutritional disorders	*105 (21.8)*	*5 (21.7)*	*110 (21.8)*
Weight increase	83 (17.3)	4 (17.4)	87 (17.3)

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3.2. Serious adverse events

Serious adverse events reported for ≥ 5 subjects are shown below.

Total no. subj. with treatment	Risperidone 481	RIS (CAN-19) 23	All Subjects 504
Total no. subj. with adverse event	**63 (13.1)**	**4 (17.4)**	**67 (13.3)**
Body as a whole - general disorders	*21 (4.4)*	*2 (8.7)*	*23 (4.6)*
Condition aggravated	11 (2.3)	2 (8.7)	13 (2.6)
Psychiatric disorders	*16 (3.3)*	*1 (4.3)*	*17 (3.4)*
Aggressive reaction	9 (1.9)	1 (4.3)	10 (2.0)

3.3. Death

None of the subjects died during the trial.

3.4. Number(%) of subjects with EPS-related adverse events

EPS related adverse events include: tremor, dystonia, hypokinesia, hypertonia, hyperkinesia, oculogyric crisis, abnormal gait, ataxia, muscle contractions involuntary, hyporeflexia, akathisia, dyskinesia, dyskinesia tardive, tetany, tongue paralysis, bradykinesia, and extrapyramidal disorder.

	Risperidone	RIS (CAN-19)	All Subjects
Total no. subj. with treatment	481	23	504
Total no. subj. with EPS AEs	104 (21.6)	4 (17.4)	108 (21.4)
Extrapyramidal disorder	27 (5.6)	0 (0.0)	27 (5.6)
Tremor	21 (4.4)	1 (4.3)	22 (4.4)
Hypertonia	20 (4.2)	1 (4.3)	21 (4.2)
Hypokinesia	20 (4.2)	1 (4.3)	21 (4.2)
Hyperkinesia	19 (4.0)	1 (4.3)	20 (4.0)
Dyskinesia	14 (2.9)	1 (4.3)	15 (3.0)
Bradykinesia	14 (2.9)	0 (0.0)	14 (2.8)
Dystonia	9 (1.9)	0 (0.0)	9 (1.8)
Gait abnormal	9 (1.9)	0 (0.0)	9 (1.8)
Oculogyric crisis	5 (1.0)	0 (0.0)	5 (1.0)
Dyskinesia tardive	2 (0.4)	0 (0.0)	2 (0.4)

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3.5. Number(%) of subjects with prolactin-related adverse events

Prolactin related adverse events include: gynaecomastia, lactation nonpuerperal, breast discharge, impotence, libido decreased, breast pain male, breast pain female, anorgasmia, dysmenorrhoea, ejaculation failure, sexual function abnormal and hyperprolactinaemia.

Total no. subj. with treatment	**Risperidone 481**	**RIS (CAN-19) 23**	**All Subjects 504**
Total no. subj. with adverse event	**73 (15.2)**	**6 (26.1)**	**79 (15.7)**
Endocrine disorders	*70 (14.6)*	*6 (26.1)*	*76 (15.1)*
Hyperprolactinaemia	51 (10.6)	5 (21.7)	56 (11.1)
Gynaecomastia	22 (4.6)	2 (8.7)	24 (4.8)
Reproductive disorders, female	*2 (0.4)*	*0 (0.0)*	*2 (0.4)*
Dysmenorrhoea	1 (0.2)	0 (0.0)	1 (0.2)
Lactation nonpuerperal	1 (0.2)	0 (0.0)	1 (0.2)
Reproductive disorders, male	*1 (0.2)*	*0 (0.0)*	*1 (0.2)*
Sexual function abnormal	1 (0.2)	0 (0.0)	1 (0.2)

3.6. Prolactin results by sex (New patients)

Prolactin levels at endpoint and at Month 12 are summarized below by sex.

Time point (Re-assessment time)	Risperidone (n=481)				
	No. paired	Reference time (Open: screening)		Re-assessment time	
		Mean ± SE	Median	Mean ± SE	Median
Males					
Month 12	237	7.3 ± 0.43	5.1	15.2 ± 0.65	13.2
Endpoint	352	7.4 ± 0.36	5.1	16.2 ± 0.64	13.6
Females					
Month 12	34	9.6 ± 1.1	7.0	19.9 ± 1.99	18.5
Endpoint	65	10.1 ± 1.0	7.2	19.9 ± 1.72	18.6

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3.7. Body weight and height

The changes from baseline of weight, height and BMI are summarized below.

	All Subjects (n=504)			
			Change from open label baseline	
	N	Mean ± SE	Mean ± SE	95% CI
Body weight (kg)				
Baseline	497	36.4 ± 0.61		
Month 12	364	43.1 ± 0.79	7.6 ± 0.25	(7.1 ; 8.0)
Endpoint	487	43.4 ± 0.71	7.0 ± 0.22	(6.6 ; 7.4)
Body height (cm)				
Baseline	466	140.1 ± 0.74		
Month 12	364	146.3 ± 0.81	6.9 ± 0.16	(6.6 ; 7.2)
Endpoint	486	145.8 ± 0.72	6.0 ± 0.16	(5.6 ; 6.3)
Body mass index (kg/m^2)				
Baseline	486	17.9 ± 0.16		
Month 12	364	19.5 ± 0.21	1.9 ± 0.10	(1.7 ; 2.1)
Endpoint	487	19.8 ± 0.19	1.8 ± 0.09	(1.6 ; 2.0)

3.8. ECG

3.8.1. DISTRIBUTION OF BORDERLINE AND PROLONGED QTc INTERVALS

	All Subjects (N=504)								
		Normal		Borderline		Prolonged		Pathological	
	N	n	(%)	n	(%)	n	(%)	n	(%)
QTcB									
Screening	475	446	(93.9)	26	(5.5)	2	(0.4)	1	(0.2)
Month 6	392	361	(92.1)	26	(6.6)	5	(1.3)	0	(0.0)
Month 12	340	312	(91.8)	25	(7.4)	3	(0.9)	0	(0.0)
Endpoint	447	412	(92.2)	31	(6.9)	4	(0.9)	0	(0.0)
QTcF									
Screening	475	473	(99.6)	1	(0.2)	1	(0.2)	0	(0.0)
Month 6	392	388	(99.0)	3	(0.8)	1	(0.3)	0	(0.0)
Month 12	340	339	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)
Endpoint	447	445	(99.6)	2	(0.4)	0	(0.0)	0	(0.0)
QTcL									
Screening	474	472	(99.6)	0	(0.0)	1	(0.2)	1	(0.2)
Month 6	392	384	(98.0)	7	(1.8)	1	(0.3)	0	(0.0)
Month 12	340	336	(98.8)	4	(1.2)	0	(0.0)	0	(0.0)
Endpoint	447	442	(98.9)	5	(1.1)	0	(0.0)	0	(0.0)
QTcL_2									
Screening	474	469	(98.9)	3	(0.6)	1	(0.2)	1	(0.2)
Month 6	392	378	(96.4)	12	(3.1)	2	(0.5)	0	(0.0)
Month 12	340	331	(97.4)	9	(2.6)	0	(0.0)	0	(0.0)
Endpoint	447	434	(97.1)	13	(2.9)	0	(0.0)	0	(0.0)

Normal: male <430, female <450
Borderline: male 430-450, female 450-470
Prolonged: male >450-500, female >470-500
Pathological: > 500

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3.8.2. DISTRIBUTION OF INCREASES FROM OPEN-LABEL BASELINE IN ECG VALUES

QTc intervals	Time point	N	All Subjects (N=504)					
			< 30 ms		30-60 ms		> 60 ms	
			n	(%)	n	(%)	n	(%)
QTcB	Month 6	375	323	(86.1)	49	(13.1)	3	(0.8)
	Month 12	324	271	(83.6)	51	(15.7)	2	(0.6)
	Endpoint	422	361	(85.5)	59	(14.0)	2	(0.5)
QTcF	Month 6	375	332	(88.5)	40	(10.7)	3	(0.8)
	Month 12	324	278	(85.8)	46	(14.2)	0	(0.0)
	Endpoint	422	372	(88.2)	50	(11.8)	0	(0.0)
QTcL	Month 6	375	357	(95.2)	17	(4.5)	1	(0.3)
	Month 12	324	305	(94.1)	19	(5.9)	0	(0.0)
	Endpoint	421	399	(94.8)	22	(5.2)	0	(0.0)
QTcL_2	Month 6	375	352	(93.9)	21	(5.6)	2	(0.5)
	Month 12	324	307	(94.8)	16	(4.9)	1	(0.3)
	Endpoint	421	401	(95.2)	19	(4.5)	1	(0.2)

3.8.3. VITAL SIGNS

Mean and mean change of vital signs findings from open label baseline at month 12 and endpoint are summarized below.

	All Subjects (n=504)			
			Change from open label baseline	
	N	Mean ± SE	Mean ± SE	95% CI
Body temperature (degree Celsius)				
Baseline	459	36.4 ± 0.02		
Month 12	339	36.4 ± 0.03	-0.03 ± 0.03	(-0.1 ; -0.0)
Endpoint	474	36.4 ± 0.02	-0.01 ± 0.03	(-0.1 ; -0.0)
Systolic blood pressure (mmHg)				
Baseline	498	103.1 ± 0.57		
Month 12	368	105.6 ± 0.67	3.3 ± 0.60	(2.2 ; 4.5)
Endpoint	504	106.1 ± 0.58	3.0 ± 0.53	(2.0 ; 4.0)
Diastolic blood pressure (mmHg)				
Baseline	498	65.9 ± 0.45		
Month 12	367	67.3 ± 0.54	2.0 ± 0.60	(0.8 ; 3.2)
Endpoint	504	67.6 ± 0.46	1.8 ± 0.50	(0.9 ; 2.8)
Pulse rate (bpm)				
Baseline	498	81.9 ± 0.53		
Month 12	368	80.2 ± 0.62	-1.6 ± 0.74	(-3.1 ; -0.2)
Endpoint	504	81.3 ± 0.54	-0.6 ± 0.64	(-1.9 ; 0.6)
Respiration rate (1/min)				
Baseline	492	20.9 ± 0.25		
Month 12	363	20.6 ± 0.20	-0.4 ± 0.30	(-1.0 ; 0.2)
Endpoint	501	20.6 ± 0.17	-0.3 ± 0.25	(-0.8 ; 0.2)

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3.9. ESRS: change from baseline to endpoint

Mean and mean change of Total ESRS from open label baseline at month 12 and endpoint are summarized below.

	All Subjects (n=504)			
Time point	N	Mean ± SE	Median (min; max)	Change from open label baseline (Mean ± SE)
Baseline	497	1.1 ± 0.14	0.0 (0.0 ; 35.0)	
Month 12	367	0.7 ± 0.10	0.0 (0.0 ; 13.0)	-0.4 ± 0.15
Endpoint	495	0.8 ± 0.10	0.0 (0.0 ; 16.0)	-0.3 ± 0.12

3.10. Cognitive function

The scores of the modified verbal learning test at endpoint and Month 12 are summarized below.

	All Subjects (n=504)			
			Change from open label baseline	
Cognitive test	N	Mean ± SE	Mean ± SE	95% CI
Total long delay free recall				
Baseline	478	5.9 ± 0.12		
Month 12	349	6.6 ± 0.13	0.8 ± 0.12	(0.6 ; 1.1)
Endpoint	442	6.6 ± 0.12	0.7 ± 0.11	(0.5 ; 1.0)
Total short delay free recall				
Baseline	478	29.5 ± 0.43		
Month 12	349	32.4 ± 0.49	2.9 ± 0.43	(2.1 ; 3.8)
Endpoint	442	32.3 ± 0.44	2.9 ± 0.39	(2.2 ; 3.7)
Total correct				
Baseline	478	17.1 ± 0.21		
Month 12	349	17.7 ± 0.23	0.8 ± 0.21	(0.4 ; 1.2)
Endpoint	442	17.7 ± 0.20	0.7 ± 0.19	(0.3 ; 1.1)

Higher scores indicate better condition for all three parameters.

Similar results were seen in the continuous performance test scores.

JJRE 02297155
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