Clinical trial results:
From Immediate-release MPH (Methylphenidate) to OROS MPH (Osmotic Release Oral Delivery System Methylphenidate): The Impact Upon Family of Children and Adolescents With ADHD (Attention Deficit Hyperactivity Disorder)

Summary

EudraCT number	2015-001216-35
Trial protocol	Outside EU/EEA
Global end of trial date	23 July 2008

Results information

Result version number	v1
This version publication date	29 January 2016
First version publication date	29 January 2016

Trial information

Trial identification

Sponsor protocol code	CONCERTAATT4086

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00758160
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Johnson & Johnson Taiwan Ltd
Sponsor organisation address	8F, 319 Tun Hwa S. Rd, Sec. 2, Taipei, Taiwan,
Public contact	Clinical Registry Group-JB BV, Janssen Research and Development, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group-JB BV, Janssen Research and Development, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 July 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 July 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate whether familial relationships and psychological status of Subjects or caregivers as well as Attention Deficit Hyperactivity Disorder (ADHD) symptoms ofSubjects can be improved by switching from Immediate-release Methylphenidate (IR-MPH) to Osmotic Release Oral Delivery System Methylphenidate (OROS-MPH)

Protection of trial subjects:

Safety assessments included of monitoring and recording all adverse events and serious adverse events, the regular measurement of vital signs and the performance of physical examinations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 February 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Taiwan: 296
Worldwide total number of subjects	296
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	215
Adolescents (12-17 years)	80
Adults (18-64 years)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total 296 subjects were enrolled in this study from 10 study center. Out of 296 subjects 67 subjects withdraw/terminated from the Study.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	OROS methylphenidate

Arm description:

Subjects received Osmotic Release Oral Delivery System (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks. Dose was adjusted for each participant based on clinical responses and/or side effects.

Arm type	Experimental
Investigational medicinal product name	OROS Methylphenidate
Investigational medicinal product code	
Other name	CONCERTA
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects will receive Osmotic Release Oral Delivery System (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks.

Number of subjects in period 1	OROS methylphenidate
Started	296
Completed	230
Not completed	66
Consent withdrawn by subject	8
'Administration Problems '	3
Adverse event, non-fatal	15
'No Longer Requires Study Medication '	4
Lost to follow-up	14
Lack of efficacy	10
Protocol deviation	12

Baseline characteristics

Reporting groups	
Reporting group title	Overall study
Reporting group description:	
Subjects received osmotic release oral delivery system (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks. Dose will be adjusted for each participant based on clinical responses and/or side effects.	

Reporting group values	Overall study	Total	
Number of subjects	296	296	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	215	215	
Adolescents (12-17 years)	80	80	
Adults (18-64 years)	1	1	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	9.5		
standard deviation	± 2.4	-	
Gender categorical Units: Subjects			
Female	49	49	
Male	247	247	

End points

End points reporting groups

Reporting group title	OROS methylphenidate

Reporting group description:

Subjects received Osmotic Release Oral Delivery System (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks. Dose was adjusted for each participant based on clinical responses and/or side effects.

Subject analysis set title	Intent-to-treat (ITT) population
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Intent-to-treat (ITT) analysis set included all Subjects who received OROS-MPH at least once and provided at least 1 post-baseline efficacy measurement.

Primary: Mean Change From Baseline in Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Parents) Score at Week 2

End point title	Mean Change From Baseline in Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Parents) Score at Week 2[1]

End point description:

Parents were asked to assess their children on a 26-item Chinese SNAP-IV questionnaire consisting of inattention (items 1-9; subscore range 0-27), hyperactivity (items 10-18; subscore range 0-27) and oppositional (19-26, subscore range 0-24) subscales used to assess the qualitative judgments in Attention Deficit Hyperactivity Disorder (ADHD). Each item was based on a 4-point likert scale ranging from 0 (not at all) to 3 (very much). The overall score ranged from 0 to 78. The total score for Inattention and hyperactivity ranged from 0 to 27 and for oppositional ranged from 0 to 21. Mean Change was calculated as mean SNAP-IV score at Week 2 minus mean SNAP-IV score at Baseline. Here 'n' included those Subjects who were evaluable for this measure at the specified time point.

End point type	Primary

End point timeframe:

Baseline and Week 2

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not reported for this endpoint as inferential analysis was not planned.

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	296[2]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: Inattention (n = 293)	1.7 (± 0.6)			
Baseline: Hyperactivity (n = 293)	1.4 (± 0.7)			
Baseline: Oppositional (n = 296)	1.3 (± 0.7)			
Change at Week 2: Inattention (n = 293)	-0.4 (± 0.5)			
Change at Week 2: Hyperactivity (n = 293)	-0.3 (± 0.5)			
Change at Week 2: Oppositional (n = 296)	-0.3 (± 0.5)			

Notes:

[2] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean Change From Baseline in Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Parents) Score at Week 4

End point title	Mean Change From Baseline in Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Parents) Score at Week 4[3]

End point description:

Parents were asked to assess their children on a 26-item Chinese SNAP-IV questionnaire consisting of inattention (items 1-9; subscore range 0-27), hyperactivity (items 10-18; subscore range 0-27) and oppositional (19-26, subscore range 0-24) subscales used to assess the qualitative judgments in Attention Deficit Hyperactivity Disorder (ADHD). Each item was based on a 4-point likert scale ranging from 0 (not at all) to 3 (very much). The overall score ranged from 0 to 78. The total score for Inattention and hyperactivity ranged from 0 to 27 and for oppositional ranged from 0 to 21. Mean Change was calculated as mean SNAP-IV score at Week 4 minus mean SNAP-IV score at Baseline. Here 'n' included those Subjects who were evaluable for this measure at the specified time point.

End point type	Primary

End point timeframe:

Baseline and Week 4

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not reported for this endpoint as inferential analysis was not planned.

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	296[4]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 4: Inattention (n = 293)	-0.4 (± 0.6)			
Change at Week 4: Hyperactivity (n = 293)	-0.3 (± 0.6)			
Change at Week 4: Oppositional (n = 296)	-0.3 (± 0.6)			

Notes:

[4] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean Change From Baseline in Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Parents) Score at Week 8

End point title	Mean Change From Baseline in Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Parents) Score at Week 8[5]

End point description:

Parents were asked to assess their children on a 26-item Chinese SNAP-IV questionnaire consisting of inattention (items 1-9; subscore range 0-27), hyperactivity (items 10-18; subscore range 0-27) and oppositional (19-26, subscore range 0-24) subscales used to assess the qualitative judgments in Attention Deficit Hyperactivity Disorder (ADHD). Each item was based on a 4-point likert scale ranging from 0 (not at all) to 3 (very much). The overall score ranged from 0 to 78. The total score for Inattention and hyperactivity ranged from 0 to 27 and for oppositional ranged from 0 to 21. Mean

Change was calculated as mean SNAP-IV score at Week 8 minus mean SNAP-IV score at Baseline. Here 'n' included those Subjects who were evaluable for this measure at the specified time point.

End point type	Primary

End point timeframe:

Baseline and Week 8

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not reported for this endpoint as inferential analysis was not planned.

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	296[6]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 8: Inattention (n = 293)	-0.5 (± 0.6)			
Change at Week 8: Hyperactivity (n = 293)	-0.4 (± 0.6)			
Change at Week 8: Oppositional (n = 296)	-0.4 (± 0.6)			

Notes:

[6] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean Change From Baseline in Chinese Health Questionnaire (CHQ) at Week 4

End point title	Mean Change From Baseline in Chinese Health Questionnaire (CHQ) at Week 4[7]

End point description:

The CHQ is a self administered screening instrument used to assess psychiatric morbidity in the Chinese community. It was derived from the General Health Questionnaire, and has been validated with satisfactory construct validity and applied in the survey of psychiatric morbidity in the community and in hospital settings. Four factors are included in the structure: somatic symptoms; anxiety and worrying; sleep problems; and depression and poor family relationships. It contains 12 items, with a maximum score of 12. CHQ scores indicated the severity of Subjects' psychological problems (0–2=normal; 3–4=minor; 5–6=moderate; and 7–12=severe psychological problems). Mean Change was calculated as mean CHQ score at Week 4 minus mean CHQ score at Baseline. 'N' (number of Subjects analysed) included those Subjects who were evaluable for this measure and 'n' included those Subjects who were evaluable for this measure at specified time point.

End point type	Primary

End point timeframe:

Baseline and Week 4

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not reported for this endpoint as inferential analysis was not planned.

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	275[8]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: Mother Assessment (n = 275)	1.9 (± 0.6)			
Baseline: Father Assessment (n = 216)	1.7 (± 0.4)			
Change at Week 4: Mother Assessment (n = 275)	-0.1 (± 0.4)			
Change at Week 4: Father Assessment (n = 216)	0 (± 0.3)			

Notes:

[8] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Mean Change From Baseline in Chinese Health Questionnaire (CHQ) at Week 8

End point title	Mean Change From Baseline in Chinese Health Questionnaire (CHQ) at Week 8[9]

End point description:

The CHQ is a self administered screening instrument used to assess psychiatric morbidity in the Chinese community. It was derived from the General Health Questionnaire, and has been validated with satisfactory construct validity and applied in the survey of psychiatric morbidity in the community and in hospital settings. Four factors are included in the structure: somatic symptoms; anxiety and worrying; sleep problems; and depression and poor family relationships. It contains 12 items, with a maximum score of 12. CHQ scores indicated the severity of Subjects psychological problems (0–2=normal; 3–4=minor; 5–6=moderate; and 7–12=severe psychological problems). Mean Change was calculated as mean CHQ score at Week 8 minus mean CHQ score at Baseline. 'N' (number of Subjects analyzed) included those subjects who were evaluable for this measure. Here 'n' included those Subjects who were evaluable for this measure at specified time point.

End point type	Primary

End point timeframe:

Baseline and Week 8

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not reported for this endpoint as inferential analysis was not planned.

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	275[10]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 8: Mother Assessment (n = 275)	-0.1 (± 0.4)			
Change at Week 8: Father Assessment (n = 216)	0 (± 0.4)			

Notes:
[10] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Chinese Version of the Family Adaptation, Partnership, Growth, Affection, and Resolve (Family APGAR-C) Score

End point title	Chinese Version of the Family Adaptation, Partnership, Growth, Affection, and Resolve (Family APGAR-C) Score

End point description:

Parents of the Subjects were asked to assess the Family APGAR which is a 5-item questionnaire designed to assess the 5 dimensions of perceived family support: Adaptation, Partnership, Growth, Affection, and Resolve. Each item is rated on a 3-point scale ranging from 0 to 2 where 0=hardly ever, 1=some of the time and 2=almost always. The total score ranges from 0 to 10 with greater scores indicating greater family support. Here 'N' (number of Subjects analysed) included those Subjects who were evaluable for this measure and 'n' included those Subjects who were evaluable for this measure at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 4 and 8

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	281[11]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: Mother Assessment (n = 275)	6.4 (± 2.9)			
Baseline: Father Assessment (n = 216)	6.5 (± 2.5)			
Week 4: Mother Assessment (n = 280)	6.6 (± 2.8)			
Week 4: Father Assessment (n = 223)	6.7 (± 2.5)			
Week 8: Mother Assessment (n = 281)	6.5 (± 3)			
Week 8: Father Assessment (n = 226)	6.6 (± 2.7)			

Notes:
[11] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Teachers) Score

End point title	Swanson, Nolan and Pelham-Fourth Edition (SNAP-IV) Rating Scale (Teachers) Score

End point description:

Teachers were asked to assess the children on a 26-item Chinese SNAP-IV questionnaire consisting of inattention (items 1-9; subscore range 0-27), hyperactivity (items 10-18; subscore range 0-27) and oppositional (19-26, subscore range 0-24) subscales used to assess the qualitative judgments in Attention Deficit Hyperactivity Disorder (ADHD). Each item was based on a 4-point likert scale ranging from 0 (not at all) to 3 (very much). The overall score ranged from 0 to 78. The total score for Inattention and hyperactivity ranged from 0 to 27 and for oppositional ranged from 0 to 21. Here 'N' (number of Subjects analysed) included those Subjects who were evaluable for this measure. 'n' included those Subjects who were evaluable for this measure at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4 and 8

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	288[12]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline: Inattention (n = 281)	1.5 (± 0.7)			
Baseline:Hyperactivity (n = 285)	1.1 (± 0.7)			
Baseline: Oppositional (n = 283)	0.9 (± 0.7)			
Week 2: Inattention (n = 286)	1.3 (± 0.7)			
Week 2: Hyperactivity (n = 287)	0.9 (± 0.7)			
Week 2: Oppositional (n = 286)	0.7 (± 0.7)			
Week 4: Inattention (n = 287)	1.2 (± 0.6)			
Week 4: Hyperactivity (n = 288)	0.9 (± 0.8)			
Week 4: Oppositional (n = 287)	0.7 (± 0.7)			
Week 8: Inattention (n = 287)	1.1 (± 0.6)			
Week 8: Hyperactivity (n = 288)	0.8 (± 0.7)			
Week 8: Oppositional (n = 287)	0.7 (± 0.7)			

Notes:

[12] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Social Adjustment Scale Score for Children and Adolescents (SAICA)

End point title	Social Adjustment Scale Score for Children and Adolescents (SAICA)

End point description:

SAICA is a 77-item semi-structured interview scale designed for administration to school-aged children with age 6-18 years, or to their parents about their children. SAICA provides an evaluation of children's current functioning in the domains of school, spare time, peer relations, and home behaviors. Each item ranged on a 4-point likert scale ranging from 1 to 4 with a higher mean score indicating either poorer social function or a more severe social problem. Here 'N' (number of Subjects analyzed) included those Subjects who were evaluable for this measure. 'n' included those Subjets who were evaluable for this measure at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 4 and Week 8

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	165[13]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n = 151)	1.5 (± 0.7)			
Week 4 (n = 160)	1.8 (± 0.3)			
Week 8 (n = 165)	1.8 (± 0.3)			

Notes:

[13] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Global Impression-Severity (CGI-S) Score

End point title	Clinical Global Impression-Severity (CGI-S) Score

End point description:

CGI-ADHD-S is a single item assessment of the global severity of ADHD symptoms in relation to the clinician's total experience after reviewing all the returned questionnaires and clinical assessment of Subjects' behavioral symptoms. Severity is rated on a 7-point scale ranging from 1 to 7 with 1=normal (not at all ill) and 7=most extremely ill. Here 'N' (number of Subjects analysed) included those Subjects who were evaluable for this measure. 'n' included those Subjects who were evaluable for this measure at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4 and 8

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	292[14]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n = 290)	4.3 (± 0.9)			
Week 2 (n = 291)	3.5 (± 1)			
Week 4 (n = 291)	3.1 (± 1.1)			
Week 8 (n = 292)	3 (± 1.1)			

Notes:

[14] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Clinical Global Impression-Improvement (CGI-I) Score

End point title	Number of Participants With Clinical Global Impression-Improvement (CGI-I) Score

End point description:

CGI-I is a single item assessment of the global improvement of ADHD symptoms in relation to the clinician's total experience after reviewing all the returned questionnaires and clinical assessment of participants' behavioral symptoms. Improvement is rated on a 7-point scale (1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, and 7=very much worse). Here 'N' (number of Subjects analysed) included those subjects who were evaluable for this measure. 'n' included those subjects who were evaluable for this measure at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4 and 8

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	292[15]			
Units: Participants				
number (not applicable)				
Week 2: Very much improved (n = 292)	4			
Week 2: Much improved (n = 292)	98			
Week 2: Minimally improved (n = 292)	126			
Week 2: No change (n = 292)	45			
Week 2: Minimally worse (n = 292)	16			
Week 2: Much worse (n = 292)	2			
Week 2: Very much worse (n = 292)	1			
Week 4: Very much improved (n = 262)	15			
Week 4: Much improved (n = 262)	111			
Week 4: Minimally improved (n = 262)	96			
Week 4: No change (n = 262)	27			
Week 4: Minimally worse (n = 262)	10			
Week 4: Much worse (n = 262)	13			
Week 4: Very much worse (n = 262)	0			
Week 8: Very much improved (n = 282)	16			
Week 8: Much improved (n = 282)	129			
Week 8: Minimally improved (n = 282)	91			
Week 8: No change (n = 282)	28			
Week 8: Minimally worse (n = 282)	13			
Week 8: Much worse (n = 282)	4			
Week 8: Very much worse (n = 282)	1			

Notes:

[15] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Global Assessment of Satisfaction by Parents/Caregivers

End point title	Global Assessment of Satisfaction by Parents/Caregivers

End point description:

Parents/caregivers were asked to assess the satisfaction with respect to ADHD treatment on a 5-point scale ranging from 1 to 5 where 1=completely dissatisfied, 2=somewhat dissatisfied, 3=neutral, 4=somewhat satisfied, and 5=completely satisfied. Here 'N' (number of subjects analysed) included those Subjects who were evaluable for this measure. 'n' included those subjects who were evaluable for this measure at specified time point.

End point type	Secondary

End point timeframe:

Standard Deviation

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	291[16]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n = 290)	3.1 (± 0.9)			
Week 2 (n = 291)	3.4 (± 0.8)			
Week 4 (n = 291)	3.7 (± 0.8)			
Week 8 (n = 291)	3.6 (± 0.9)			

Notes:

[16] - ITT Population

Statistical analyses

No statistical analyses for this end point

Secondary: Global Assessment of Satisfaction by Subject

End point title	Global Assessment of Satisfaction by Subject

End point description:

Subjects were asked to assess their satisfaction with respect to ADHD treatment on a 5-point scale ranging from 1 to 5 where 1=completely dissatisfied, 2=somewhat dissatisfied, 3=neutral, 4=somewhat satisfied and 5=completely satisfied. Here 'N' (number of subjects analysed) included those subjects who were evaluable for this measure. 'n' included those subjects who were evaluable for this measure at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Week 2, 4 and 8

End point values	OROS methylphenidate			
Subject group type	Reporting group			
Number of subjects analysed	291[17]			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n = 290)	3.2 (± 0.9)			
Week 2 (n = 291)	3.5 (± 0.8)			
Week 4 (n = 291)	3.7 (± 0.8)			
Week 8 (n = 291)	3.6 (± 0.9)			

Notes:

[17] - ITT Po

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline upto End of treatment

Adverse event reporting additional description:

Adverse events(AEs) data was reported for each visit as total data for AEs were not analyzed. In addition to the AEs reported in the below table, a category of AEs titled "Other" was reported as no dictionary was used and events under this category were not further specified. Total # affected by other AEs is minimum number of participants affected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	No dictionary use
Dictionary version	0

Reporting groups

Reporting group title	OROS MPH-Baseline

Reporting group description:

Subjects received Osmotic Release Oral Delivery System (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks. Dose was adjusted for each subject based on clinical responses and/or side effects.

Reporting group title	OROS MPH-Week 2

Reporting group description:

Subjects received Osmotic Release Oral Delivery System (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks. Dose was adjusted for each subject based on clinical responses and/or side effects.

Reporting group title	OROS MPH-Week 4

Reporting group description:

Subjects received Osmotic Release Oral Delivery System (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks. Dose was adjusted for each subject based on clinical responses and/or side effects.

Reporting group title	OROS MPH-Week 8

Reporting group description:

Subjects received Osmotic Release Oral Delivery System (OROS) methylphenidate (MPH) 18 milligram (mg), 36 mg or 54 mg once daily for 8 weeks. Dose was adjusted for each subject based on clinical responses and/or side effects.

Serious adverse events	OROS MPH-Baseline	OROS MPH-Week 2	OROS MPH-Week 4
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 296 (0.00%)	0 / 296 (0.00%)	0 / 296 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	OROS MPH-Week 8		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 296 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from	0		

adverse events

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	OROS MPH-Baseline	OROS MPH-Week 2	OROS MPH-Week 4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	80 / 296 (27.03%)	100 / 296 (33.78%)	90 / 296 (30.41%)
General disorders and administration site conditions			
Appetite decreased			
subjects affected / exposed	80 / 296 (27.03%)	100 / 296 (33.78%)	90 / 296 (30.41%)
occurrences (all)	81	101	91
Nausea			
subjects affected / exposed	22 / 296 (7.43%)	22 / 296 (7.43%)	15 / 296 (5.07%)
occurrences (all)	22	22	15
Insomnia			
subjects affected / exposed	22 / 296 (7.43%)	35 / 296 (11.82%)	30 / 296 (10.14%)
occurrences (all)	23	35	30
Headache			
subjects affected / exposed	17 / 296 (5.74%)	14 / 296 (4.73%)	8 / 296 (2.70%)
occurrences (all)	17	14	8
Dizziness			
subjects affected / exposed	17 / 296 (5.74%)	14 / 296 (4.73%)	8 / 296 (2.70%)
occurrences (all)	12	10	6
Somnolence			
subjects affected / exposed	8 / 296 (2.70%)	4 / 296 (1.35%)	2 / 296 (0.68%)
occurrences (all)	8	4	2
Abdominal pain			
subjects affected / exposed	17 / 296 (5.74%)	20 / 296 (6.76%)	11 / 296 (3.72%)
occurrences (all)	17	20	11
Stomachache			
subjects affected / exposed	5 / 296 (1.69%)	4 / 296 (1.35%)	1 / 296 (0.34%)
occurrences (all)	5	4	1

Non-serious adverse events	OROS MPH-Week 8		

Total subjects affected by non-serious adverse events subjects affected / exposed	95 / 296 (32.09%)		
General disorders and administration site conditions			
Appetite decreased			
subjects affected / exposed	95 / 296 (32.09%)		
occurrences (all)	95		
Nausea			
subjects affected / exposed	15 / 296 (5.07%)		
occurrences (all)	15		
Insomnia			
subjects affected / exposed	25 / 296 (8.45%)		
occurrences (all)	25		
Headache			
subjects affected / exposed	7 / 296 (2.36%)		
occurrences (all)	7		
Dizziness			
subjects affected / exposed	7 / 296 (2.36%)		
occurrences (all)	9		
Somnolence			
subjects affected / exposed	1 / 296 (0.34%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	12 / 296 (4.05%)		
occurrences (all)	12		
Stomachache			
subjects affected / exposed	1 / 296 (0.34%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported