



Clinical trial results:

A Double-Blind Placebo Controlled Study of Atomoxetine Hydrochloride for the Treatment of ADHD in Children and Adolescents With ADHD and Comorbid Dyslexia

Summary

EudraCT number	2017-000739-15
Trial protocol	Outside EU/EEA
Global end of trial date	25 February 2011

Results information

Result version number	v1 (current)
This version publication date	22 December 2021
First version publication date	22 December 2021

Trial information

Trial identification

Sponsor protocol code	B4Z-US-LYEB
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00607919
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 11672

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877 CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877 2854559,

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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 February 2011
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	25 February 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study is to evaluate the effect of atomoxetine in treating Attention-Deficit/Hyperactivity Disorder (ADHD) symptoms in children and adolescents with ADHD and comorbid reading disability (dyslexia)

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 March 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	United States: 209
Worldwide total number of subjects	209
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)	0
Adolescents (12-17 years)	209
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study comprised a 16-week placebo-controlled, double-blind acute phase and followed by an optional 16-week open-label in which all participants were treated with Atomoxetine.

Period 1

Period 1 title	Acute Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Atomoxetine/Atomoxetine

Arm description:

Participants were assigned to Atomoxetine treatment in both acute and open-label phase. Atomoxetine was administered at 1.0 to 1.4 milligram/kilogram/day (mg/kg/day) given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Arm type	Experimental
Investigational medicinal product name	Atomoxetine
Investigational medicinal product code	
Other name	LY139603
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Atomoxetine administered at 1.0 to 1.4 mg/kg/day given orally once daily in the morning for 16 to 32 weeks.

Arm title	Placebo/Atomoxetine
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Arm description:

Participants were assigned to placebo in acute phase and Atomoxetine in open-label phase. Placebo was packaged in the same way as Atomoxetine, and administered orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo was administered oral, daily, for 16 weeks.

Number of subjects in period 1	Atomoxetine/Atomoxetine	Placebo/Atomoxetine
Started	120	89
Completed	86	73
Not completed	34	16
Parent/Caregiver Decision	6	4
Consent withdrawn by subject	3	3
Adverse event, non-fatal	9	2
Lost to follow-up	9	3
Entry Criteria Not Met	1	1
Lack of efficacy	1	2
Protocol deviation	5	1

Period 2

Period 2 title	Open-Label Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Atomoxetine/Atomoxetine

Arm description:

Participants were assigned to Atomoxetine treatment in both acute and open-label phase. Atomoxetine was administered at 1.0 to 1.4 milligram/kilogram/day (mg/kg/day) given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Arm type	Experimental
Investigational medicinal product name	Atomoxetine
Investigational medicinal product code	
Other name	LY139603
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Atomoxetine was administered at 1.0 to 1.4 mg/kg/day given orally once daily in the morning for 16 to 32 weeks.

Arm title	Placebo/Atomoxetine
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Arm description:

Participants were assigned to placebo in acute phase and Atomoxetine in open-label phase. Placebo was packaged in the same way as Atomoxetine, and administered orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Arm type	Active comparator
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo was administered oral, daily, for 16 weeks.

Number of subjects in period 2^[1]	Atomoxetine/Atomoxetine	Placebo/Atomoxetine
Started	84	71
Completed	74	59
Not completed	10	12
Parent/Caregiver Decision	1	2
Consent withdrawn by subject	2	2
Adverse event, non-fatal	1	5
Lost to follow-up	4	1
Protocol deviation	2	2

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Two participants completed acute phase but did not continue into open-label.

Baseline characteristics

Reporting groups

Reporting group title	Atomoxetine/Atomoxetine
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Reporting group description:

Participants were assigned to Atomoxetine treatment in both acute and open-label phase. Atomoxetine was administered at 1.0 to 1.4 milligram/kilogram/day (mg/kg/day) given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Reporting group title	Placebo/Atomoxetine
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Reporting group description:

Participants were assigned to placebo in acute phase and Atomoxetine in open-label phase. Placebo was packaged in the same way as Atomoxetine, and administered orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Reporting group values	Atomoxetine/Atomoxetine	Placebo/Atomoxetine	Total
Number of subjects	120	89	209
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	12.24 ± 1.72	12.44 ± 1.90	-
Gender categorical Units: Subjects			
Female	46	34	80
Male	74	55	129
Race/Ethnicity Units: Subjects			
African	13	11	24
Caucasian	86	66	152
East Asian	2	1	3
Hispanic	18	11	29
West Asian	1	0	1

End points

End points reporting groups

Reporting group title	Atomoxetine/Atomoxetine
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Reporting group description:

Participants were assigned to Atomoxetine treatment in both acute and open-label phase. Atomoxetine was administered at 1.0 to 1.4 milligram/kilogram/day (mg/kg/day) given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Reporting group title	Placebo/Atomoxetine
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Reporting group description:

Participants were assigned to placebo in acute phase and Atomoxetine in open-label phase. Placebo was packaged in the same way as Atomoxetine, and administered orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Reporting group title	Atomoxetine/Atomoxetine
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Reporting group description:

Participants were assigned to Atomoxetine treatment in both acute and open-label phase. Atomoxetine was administered at 1.0 to 1.4 milligram/kilogram/day (mg/kg/day) given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Reporting group title	Placebo/Atomoxetine
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Reporting group description:

Participants were assigned to placebo in acute phase and Atomoxetine in open-label phase. Placebo was packaged in the same way as Atomoxetine, and administered orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Subject analysis set title	ADHD+ Dyslexia (D): Atomoxetine
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with attention-deficit/hyperactivity disorder and comorbid dyslexia (ADHD+D) treated with Atomoxetine. Atomoxetine was administered at 1.0 to 1.4 mg/kg/day given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Subject analysis set title	ADHD+ Dyslexia (D): Placebo
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with attention-deficit/hyperactivity disorder and comorbid dyslexia (ADHD+D) treated with Placebo. Placebo was packaged in the same way as Atomoxetine, and administered orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Subject analysis set title	ADHD Alone: Atomoxetine
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants with attention-deficit/hyperactivity disorder (ADHD) alone treated with Atomoxetine. Atomoxetine was administered at 1.0 to 1.4 mg/kg/day given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine

Primary: Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total Score - Parent Version at Week 16 Endpoint

End point title	Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total Score - Parent Version at Week 16 Endpoint
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End point description:

Measures the 18 symptoms contained in the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition, Text Revision (DSM-IV-TR) diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD). Individual item scores range from 0 (none/never or rarely) to 3 (severe/very often). Total scores range from 0-54. Least Square mean of change from baseline in ADHDRS is from a restricted maximum likelihood-based, mixed model repeated measures analysis which includes the effects of treatment, investigative site, baseline, visit, treatment-by-visit interaction, and baseline-by-visit interaction. Analysis Population Description (APD): All randomized participants with a baseline and at least one post-baseline result.

End point type	Primary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	47	54		
Units: units on a scale				
least squares mean (standard error)	-20.01 (\pm 1.45)	-12.27 (\pm 1.41)		

Statistical analyses

Statistical analysis title	Attention-Deficit/Hyperactivity Disorder
Comparison groups	ADHD+ Dyslexia (D): Placebo v ADHD+ Dyslexia (D): Atomoxetine
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis

Secondary: Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Parent Version at Week 16 Endpoint

End point title	Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Parent Version at Week 16 Endpoint
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End point description:

The ADHDRS-IV-Parent is an 18-item scale with 1 item for each of the 18 symptoms contained in the DSM-IV diagnosis of ADHD. Each item is scored on a 0 to 3 scale: 0=none (never or rarely); 1=mild (sometimes); 2=moderate (often); 3=severe (very often). Hyperactivity-impulsivity scores range 0-27, and inattention scores range 0-27. Total scores range from 0-54. Higher scores indicate higher impairment. APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
End point timeframe:	
Baseline, 16 weeks	

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	62	58	27	
Units: units on a scale				
arithmetic mean (standard deviation)				
Hyperactivity-Impulsivity Score	-8.23 (± 5.90)	-5.18 (± 6.01)	-6.26 (± 5.10)	
Inattention Score	-10.64 (± 7.59)	-7.79 (± 6.52)	-10.33 (± 7.95)	
Total Score	-18.87 (± 11.68)	-12.98 (± 10.75)	-16.59 (± 11.31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Teacher Version at Week 16 Endpoint

End point title	Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Teacher Version at Week 16 Endpoint
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End point description:

The ADHDRS-IV-Teacher is an 18-item scale with 1 item for each of the 18 symptoms contained in the DSM-IV diagnosis of ADHD. Each item is scored on a 0 to 3 scale: 0=none (never or rarely); 1=mild (sometimes); 2=moderate (often); 3=severe (very often). Hyperactivity-impulsivity scores range from 0-27, and inattention scores range from 0-27. Total scores range from 0-54. Higher scores indicate higher impairment. APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
End point timeframe:	
Baseline, 16 weeks	

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	22	11	
Units: units on a scale				
arithmetic mean (standard deviation)				
Hyperactivity-Impulsivity Score	-2.71 (± 3.98)	-1.99 (± 6.54)	-0.82 (± 4.92)	
Inattention Score	-4.48 (± 5.17)	-0.99 (± 5.33)	-2.27 (± 5.24)	
Total Score	-7.19 (± 6.83)	-2.98 (± 10.83)	-3.09 (± 9.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Woodcock-Johnson III Scores at Week 16 Endpoint

End point title	Change From Baseline in Woodcock-Johnson III Scores at Week 16 Endpoint
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End point description:

The Woodcock Johnson Tests of Achievement has a Standard Battery (Tests 1-12) of a broad set of scores and an Extended Battery (Tests 13-22) on specific academic strengths and weaknesses. Tests associated with reading skills (1, 2, 7, 9, 13, 17, 20) were administered. Scores for each individual test can range from 0 to over 200 where anything 69 and below is very low and anything 131 and above is very superior. Higher scores indicate better reading skills. APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	51	55	22	
Units: units on a scale				
arithmetic mean (standard deviation)				
Basic Reading Skills (Tests 1, 13)	1.75 (± 6.04)	0.87 (± 6.75)	-0.41 (± 7.99)	
Letter-Word Identification (Test 1)	1.18 (± 7.20)	-0.07 (± 6.63)	-0.32 (± 8.04)	
Passage Comprehension (Test 9)	-0.92 (± 11.43)	-1.02 (± 8.94)	-4.50 (± 9.04)	
Reading Comprehension (Test 9, 17)	-0.08 (± 9.68)	-1.09 (± 8.81)	-5.00 (± 7.45)	
Reading Fluency (Test 2)	-0.24 (± 7.91)	-0.11 (± 9.19)	1.36 (± 8.77)	
Reading Vocabulary (Test 17)	0.51 (± 8.92)	-0.16 (± 9.45)	-3.95 (± 8.60)	
Spelling (Test 7)	-0.22 (± 7.32)	-4.16 (± 12.13)	-0.41 (± 5.68)	
Spelling of Sounds (Test 20)	5.67 (± 16.07)	3.31 (± 13.49)	8.45 (± 19.78)	
Word Attack (Test 13)	2.27 (± 6.75)	1.13 (± 9.75)	-0.36 (± 7.88)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Comprehensive Test of Phonological

Processing (CTOPP) at Week 16 Endpoint

End point title	Change From Baseline in Comprehensive Test of Phonological Processing (CTOPP) at Week 16 Endpoint
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End point description:

The CTOPP assesses phonological awareness, phonological memory, and rapid naming and is appropriate for ages 7 to 24. The test contains six core subtests. The composite scores are 1) Phonological Awareness, comprised of the standard scores of the Elision and Blending Words; 2) Phonological Memory, comprised of standard scores for Memory for Digits and Non-word Repetition; and 3) Rapid Naming, comprised of standard scores for Rapid Digit Naming and Rapid Letter Naming. Standard scores range from 1-20, and composite scores range from 35-165. Higher scores are better.

End point type	Secondary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	51	55	22	
Units: units on a scale				
arithmetic mean (standard deviation)				
Blending Words	0.96 (± 1.90)	0.95 (± 1.97)	1.86 (± 1.86)	
Elision	0.88 (± 2.18)	-0.24 (± 2.34)	0.27 (± 1.91)	
Memory for Digits	0.47 (± 2.16)	0.13 (± 1.76)	-0.50 (± 1.90)	
Non-word Repetition	0.57 (± 1.79)	0.51 (± 2.00)	0.82 (± 2.52)	
Phonological Awareness	5.20 (± 9.49)	2.00 (± 9.34)	6.82 (± 11.50)	
Phonological Memory	2.22 (± 10.61)	0.96 (± 10.16)	1.36 (± 11.33)	
Rapid Digit Naming	0.26 (± 2.06)	0.16 (± 1.75)	0.23 (± 1.23)	
Rapid Letter Naming	0.31 (± 1.76)	0.24 (± 1.64)	0.14 (± 1.52)	
Rapid Naming	1.06 (± 11.00)	0.35 (± 9.75)	-0.59 (± 10.83)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Gray Oral Reading Test-4 (GORT-4) at Week 16 Endpoint

End point title	Change From Baseline in Gray Oral Reading Test-4 (GORT-4) at Week 16 Endpoint
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End point description:

The GORT-4 is a norm-referenced test of oral reading rate, accuracy, fluency, and comprehension valid for individuals aged 6 to 18 years old. The test has two parallel forms, Form A and Form B, that are administered in an alternating fashion (e.g. Week 0-Form A, Week 16-Form B, Week 32-Form A.) with each containing 14 separate stories and 5 multiple-choice comprehension questions for each story. GORT-4 yields the following scores: rate, accuracy, fluency, comprehension, and overall reading ability. Standard scores range from 1-20. Higher scores indicate better reading skills. APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	51	55	21	
Units: units on a scale				
arithmetic mean (standard deviation)				
Accuracy Score	0.71 (± 2.22)	0.40 (± 2.02)	0.95 (± 2.16)	
Comprehension Score	0.37 (± 2.35)	0.65 (± 2.50)	-0.33 (± 1.93)	
Fluency Score	0.78 (± 2.81)	0.33 (± 2.82)	1.14 (± 2.94)	
Oral Reading Quotient	-1.43 (± 23.34)	2.87 (± 20.43)	2.43 (± 10.93)	
Rate Score	0.20 (± 1.65)	0.05 (± 1.54)	0.38 (± 2.27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Test of Word Reading Efficiency (TOWRE) at Week 16 Endpoint

End point title	Change From Baseline in Test of Word Reading Efficiency (TOWRE) at Week 16 Endpoint
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End point description:

The TOWRE is a measure of an individual's ability to pronounce printed words accurately and fluently and is appropriate for individuals aged 6 to 24 years old. The TOWRE contains two subtests: Sight Word Efficiency (SWE) which assesses the number of real printed words that can be accurately identified within 45 seconds and Phonemic Decoding Efficiency (PDE) which measures the number of pronounceable printed non-words that can be accurately decoded within 45 seconds. Scores range from 45-146. Higher scores indicate higher reading proficiency. APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	61	57	26	
Units: units on a scale				
arithmetic mean (standard deviation)				
Phonemic Decoding Efficiency	1.92 (± 6.01)	1.21 (± 5.19)	1.77 (± 6.78)	
Sight Word Efficiency	1.38 (± 5.78)	1.19 (± 4.80)	0.69 (± 8.84)	

Total Word Reading Efficiency Standard Score	-0.57 (\pm 21.98)	2.81 (\pm 11.90)	-5.88 (\pm 25.98)	
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Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Working Memory Test Battery for Children (WMTB-C) at Week 16 Endpoint

End point title	Change From Baseline in Working Memory Test Battery for Children (WMTB-C) at Week 16 Endpoint
End point description: WMTB-C is assessment of working memory capacities, consisting of 9 subtests (Trials Correct Scores [Range from 55-145], Higher scores are better) reflecting 3 main components of working memory: central executive (CE) control/regulation of working memory (Backward Digit Recall, Listening Recall, Counting Recall); phonological loop (PL) responsible for holding verbal information for short periods (Digit Recall, Word List Matching, Word List Recall, Non-word List Recall); and visuo-spatial sketchpad (VSSP) which holds information in visual and spatial form (Block Recall, Mazes Memory). APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).	
End point type	Secondary
End point timeframe: Baseline, 16 weeks	

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	54	56	23	
Units: units on a scale				
arithmetic mean (standard deviation)				
Phonological Loop Component Score (n=51, 54, 21)	3.57 (\pm 10.79)	1.63 (\pm 9.00)	2.24 (\pm 9.78)	
Central Executive Component Score (n=41, 44, 12)	7.34 (\pm 10.65)	-0.89 (\pm 13.65)	2.17 (\pm 11.77)	
Visuo-Spatial Sketchpad Score (n=47, 43, 21)	4.15 (\pm 11.96)	-0.47 (\pm 12.85)	3.67 (\pm 10.77)	
Digit Recall (n=54, 56, 23)	0.17 (\pm 3.42)	0.55 (\pm 3.01)	0.22 (\pm 4.45)	
Word List Matching (n=54, 56, 23)	-0.20 (\pm 7.08)	0.05 (\pm 8.65)	2.04 (\pm 9.24)	
Word List Recall (n=54, 56, 23)	1.00 (\pm 3.29)	0.02 (\pm 3.15)	0.35 (\pm 2.98)	
Non-Word List Recall (n=53, 56, 23)	0.89 (\pm 2.74)	0.71 (\pm 2.20)	0.43 (\pm 3.53)	
Block Recall (n=54, 56, 23)	-0.37 (\pm 4.20)	-0.80 (\pm 4.18)	0.70 (\pm 4.24)	
Mazes Memory (n=54, 56, 23)	1.94 (\pm 5.90)	1.18 (\pm 5.94)	0.78 (\pm 7.33)	
Listening Recall (n=54, 56, 23)	1.52 (\pm 3.32)	1.00 (\pm 3.77)	0.04 (\pm 5.90)	
Counting Recall (n=54, 56, 23)	0.50 (\pm 4.63)	0.45 (\pm 5.07)	0.48 (\pm 5.41)	
Backward Digit Recall (n=54, 56, 23)	1.30 (\pm 3.87)	0.16 (\pm 3.62)	1.26 (\pm 4.20)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Life Participation Scale-child (LPS-C) Score at Week 16 Endpoint

End point title	Change From Baseline in Life Participation Scale-child (LPS-C) Score at Week 16 Endpoint
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End point description:

LPS-C is a short (24 item, 0-3 points per item) parent-rated scale that is designed to assess changes in adaptive functioning related to treatment for ADHD. This scale measures improvements in social, emotional, cognitive, educational, and affiliative (family, friends) functioning, which indirectly reflect improvements in executive functioning. Happy/social subscores range from 0-18, and self-control subscores range from 0-54. Total scores range from 0-72. Higher scores are better for LPS. APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	58	57	26	
Units: units on a scale				
arithmetic mean (standard deviation)				
LPS Happy/Social Score	0.57 (± 4.19)	0.53 (± 4.80)	1.38 (± 3.73)	
LPS Self Control Score	6.06 (± 8.54)	4.29 (± 10.60)	7.49 (± 8.46)	
LPS Total Score	6.51 (± 11.61)	4.82 (± 14.20)	9.05 (± 10.63)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Kiddie Sluggish Cognitive Tempo (K-SCT) at Week 16 Endpoint

End point title	Change From Baseline in Kiddie Sluggish Cognitive Tempo (K-SCT) at Week 16 Endpoint
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End point description:

The K-SCT rating scale contains 3 components: Youth, Parent, and Teacher ratings. It queries 17 candidate SCT symptoms, such as daydreams, lost in a fog, sluggish/drowsy. Scores range from 0-51. Lower scores indicate less sluggish. APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	56	57	23	
Units: units on a scale				
arithmetic mean (standard deviation)				
Total Score-Parent Variation (n= 56, 57, 23)	-7.82 (± 10.98)	-4.64 (± 9.67)	-8.24 (± 9.90)	
Total Score-Teacher Variation (n= 22, 22, 11)	-8.82 (± 11.77)	-1.64 (± 6.53)	-3.47 (± 8.83)	
Total Score-Youth Variation (n= 56, 57, 23)	-4.71 (± 9.27)	-4.21 (± 6.85)	-6.17 (± 7.71)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Multidimensional Self Concept Scale (MSCS) at Week 16 Endpoint

End point title	Change From Baseline in Multidimensional Self Concept Scale (MSCS) at Week 16 Endpoint
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End point description:

The MSCS is an overall assessment of self concept or an individual measure of any of the six scaled dimensions of self concept: Social, Competence, Affect, Academic, Family, and Physical. Standard scores range from 45-145. Higher scores are better (indicate higher self concept). APD: All randomized participants with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 16 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD+ Dyslexia (D): Placebo	ADHD Alone: Atomoxetine	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	58	57	25	
Units: units on a scale				
arithmetic mean (standard deviation)				
Academic Standard Section Score	5.91 (± 9.01)	4.23 (± 12.77)	5.52 (± 6.78)	
Affect Standard Section Score	3.62 (± 10.32)	2.35 (± 10.81)	3.56 (± 10.58)	
Competence Standard Section Score	6.64 (± 12.99)	4.95 (± 12.05)	5.20 (± 9.06)	
Family Standard Section Score	0.39 (± 12.52)	-3.12 (± 11.66)	-1.00 (± 12.26)	
Physical Standard Section Score	4.09 (± 10.34)	1.32 (± 12.06)	3.04 (± 5.99)	
Social Standard Section Score	4.36 (± 11.73)	2.72 (± 11.14)	3.88 (± 10.39)	
Standard Total Score	4.72 (± 9.47)	1.98 (± 10.19)	3.44 (± 7.70)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Parent Version at Week 32 Endpoint

End point title	Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Parent Version at Week 32 Endpoint
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End point description:

The ADHDRS-IV-parent is an 18-item scale with 1 item for each of the 18 symptoms contained in the DSM-IV diagnosis of ADHD. Each item is scored on a 0 to 3 scale: 0=none (never or rarely); 1=mild (sometimes); 2=moderate (often); 3 =severe (very often). Hyperactivity-impulsivity scores range from 0-27, and inattention scores range from 0-27. Total scores range from 0-54. Higher scores indicate higher impairment. APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
Hyperactivity-Impulsivity Score	-9.8 (± 6.17)	-8.29 (± 4.61)		
Inattention Score	-13.84 (± 6.56)	-14.33 (± 7.16)		
Total Score	-23.64 (± 10.43)	-22.62 (± 9.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Teacher Version at Week 32 Endpoint

End point title	Change From Baseline in Attention-Deficit/Hyperactivity Disorder Rating Scale (ADHDRS) Total and Subscores - Teacher Version at Week 32 Endpoint
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End point description:

The ADHDRS-IV-Teacher is an 18-item scale with 1 item for each of the 18 symptoms contained in the DSM-IV diagnosis of ADHD. Each item is scored on a 0 to 3 scale: 0=none (never or rarely); 1=mild (sometimes); 2=moderate (often); 3 =severe (very often). Hyperactivity-impulsivity scores range from 0-27, and inattention scores range from 0-27. Total scores range from 0-54. Higher scores indicate higher impairment. APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	23	9		
Units: units on a scale				
arithmetic mean (standard deviation)				
Hyperactivity-Impulsivity Score	-1.87 (± 4.80)	-2.89 (± 4.48)		
Inattention Score	-4.28 (± 6.08)	-4.19 (± 4.11)		
Total Score	-6.15 (± 8.51)	-7.08 (± 7.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Woodcock-Johnson III Scores at Week 32 Endpoint

End point title	Change From Baseline in Woodcock-Johnson III Scores at Week 32 Endpoint
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End point description:

The Woodcock Johnson Tests of Achievement has a Standard Battery (Tests 1-12) of a broad set of scores and an Extended Battery (Tests 13-22) on specific academic strengths and weaknesses. Tests associated with reading skills (1, 2, 7, 9, 13, 17, 20) were administered. Scores for each individual test can range from 0 to over 200 where anything 69 and below is very low and anything 131 and above is very superior. Higher scores indicate better reading skills. APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
Basic Reading Skills (Tests 1, 13)	2.73 (± 6.51)	-0.24 (± 5.37)		
Letter-Word Identification (Test 1)	1.69 (± 7.19)	0.24 (± 5.73)		
Passage Comprehension (Test 9)	2.31 (± 9.18)	1.24 (± 5.63)		
Reading Comprehension (Tests 9, 17)	2.89 (± 9.07)	0.86 (± 7.04)		
Reading Fluency (Test 2)	2.69 (± 9.04)	3.24 (± 8.64)		
Reading Vocabulary (Test 17)	2.60 (± 8.55)	-0.14 (± 10.57)		
Spelling (Test 7)	0.60 (± 7.74)	0.38 (± 5.96)		

Spelling of Sounds (Test 20)	2.98 (± 10.77)	5.90 (± 14.17)		
Word Attack (Test 13)	3.27 (± 7.09)	-0.90 (± 6.59)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Comprehensive Test of Phonological Processing (CTOPP) at Week 32 Endpoint

End point title	Change From Baseline in Comprehensive Test of Phonological Processing (CTOPP) at Week 32 Endpoint
End point description:	
<p>he CTOPP assesses phonological awareness, phonological memory, and rapid naming and is appropriate for ages 7 to 24. The test contains six core subtests. The composite scores are 1) Phonological Awareness, comprised of the standard scores of the Elision and Blending Words; 2) Phonological Memory, comprised of standard scores for Memory for Digits and Non-word Repetition; and 3) Rapid Naming, comprised of standard scores for Rapid Digit Naming and Rapid Letter Naming. Standard scores range from 1-20, and composite scores range from 35-165. Higher scores are better. APD included all randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).</p>	
End point type	Secondary
End point timeframe:	
Baseline, 32 weeks	

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
Blending Words	1.31 (± 2.01)	1.90 (± 2.98)		
Elision	1.07 (± 2.00)	0.71 (± 3.05)		
Memory for Digits	0.87 (± 2.17)	-0.05 (± 2.13)		
Non-word Repetition	0.93 (± 2.27)	0.43 (± 3.03)		
Phonological Awareness	7.33 (± 9.50)	5.33 (± 15.99)		
Phonological Memory	4.93 (± 10.57)	-0.67 (± 12.44)		
Rapid Digit Naming	0.43 (± 1.91)	0.62 (± 2.31)		
Rapid Letter Naming	0.43 (± 2.06)	0.90 (± 2.34)		
Rapid Naming	1.30 (± 11.27)	1.76 (± 12.35)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Gray Oral Reading Test-4 (GORT-4) at Week 32 Endpoint

End point title	Change From Baseline in Gray Oral Reading Test-4 (GORT-4) at Week 32 Endpoint
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End point description:

The GORT-4 is a norm-referenced test of oral reading rate, accuracy, fluency, and comprehension valid for individuals aged 6 to 18 years old. The test has two parallel forms, Form A and Form B, that are administered in an alternating fashion (e.g. Week 0-Form A, Week 16-Form B, Week 32-Form A.) with each containing 14 separate stories and 5 multiple-choice comprehension questions for each story. GORT-4 yields the following scores: rate, accuracy, fluency, comprehension, and overall reading ability. Standard scores range from 1-20. Higher scores indicate better reading skills. APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	20		
Units: units on a scale				
arithmetic mean (standard deviation)				
Accuracy Score	0.82 (± 1.30)	0.95 (± 1.82)		
Comprehension Score	0.04 (± 1.73)	-0.30 (± 1.59)		
Fluency Score	0.76 (± 1.40)	1.10 (± 2.63)		
Oral Reading Quotient	2.64 (± 15.05)	-1.30 (± 21.22)		
Rate Score	0.58 (± 1.74)	0.15 (± 1.98)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Test of Word Reading Efficiency (TOWRE) at Week 32 Endpoint

End point title	Change From Baseline in Test of Word Reading Efficiency (TOWRE) at Week 32 Endpoint
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End point description:

The TOWRE is a measure of an individual's ability to pronounce printed words accurately and fluently and is appropriate for individuals aged 6 to 24 years old. The TOWRE contains two subtests: Sight Word Efficiency (SWE) which assesses the number of real printed words that can be accurately identified within 45 seconds and Phonemic Decoding Efficiency (PDE) which measures the number of pronounceable printed non-words that can be accurately decoded within 45 seconds. Scores range from 45-146. Higher scores indicate higher reading proficiency. APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
Phonemic Decoding Efficiency	2.64 (± 6.54)	5.33 (± 6.98)		
Sight Word Efficiency	1.93 (± 6.51)	4.62 (± 8.74)		
Total Word Reading Efficiency Standard Score	2.56 (± 17.35)	1.52 (± 20.64)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Working Memory Test Battery for Children (WMTB-C) at Week 32 Endpoint

End point title	Change From Baseline in Working Memory Test Battery for Children (WMTB-C) at Week 32 Endpoint
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End point description:

WMTB-C is assessment of working memory capacities, consisting of 9 subtests (Trials Correct Scores [Range from 55-145], Higher scores are better) reflecting 3 main components of working memory: central executive (CE) control/regulation of working memory (Backward Digit Recall, Listening Recall, Counting Recall); phonological loop (PL) responsible for holding verbal information for short periods (Digit Recall, Word List Matching, Word List Recall, Non-word List Recall); and visuo-spatial sketchpad (VSSP) which holds information in visual and spatial form (Block Recall, Mazes Memory). APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
Phonological Loop Component Score (n=43, 20)	3.67 (± 11.27)	1.70 (± 9.66)		
Central Executive Component Score (n=38, 14)	6.53 (± 11.34)	1.64 (± 11.30)		
Visuo-Spatial Sketchpad Component Score (n=40, 20)	3.85 (± 12.89)	2.65 (± 9.96)		
Digit Recall (n=45, 21)	-0.04 (± 2.92)	0.52 (± 4.08)		

Word List Matching (n=45, 21)	2.38 (± 7.96)	1.95 (± 8.22)		
Word List Recall (n=45, 21)	1.49 (± 3.00)	0.33 (± 2.50)		
Non-Word List Recall (n=44, 21)	0.55 (± 2.90)	-0.67 (± 4.39)		
Block Recall (n=45, 21)	0.71 (± 3.88)	1.05 (± 4.24)		
Mazes Memory (n=45, 21)	2.33 (± 7.04)	3.48 (± 7.77)		
Listening Recall (n=45, 21)	2.18 (± 4.01)	-1.05 (± 6.42)		
Counting Recall (n=45, 21)	1.53 (± 4.65)	1.24 (± 6.54)		
Backward Digit Recall (n=45, 21)	1.07 (± 3.24)	2.29 (± 5.20)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Life Participation Scale-child (LPS-C) Score at Week 32 Endpoint

End point title	Change From Baseline in Life Participation Scale-child (LPS-C) Score at Week 32 Endpoint
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End point description:

LPS-C is a short (24 item, 0-3 points per item) parent-rated scale that is designed to assess changes in adaptive functioning related to treatment for ADHD. This scale measures improvements in social, emotional, cognitive, educational, and affiliative (family, friends) functioning, which indirectly reflect improvements in executive functioning. Happy/social subscores range from 0-18, and self-control subscores range from 0-54. Total scores range from 0-72. Higher scores are better for LPS. APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
LPS Happy/Social Score (n=45, 21)	1.57 (± 4.37)	2.14 (± 4.30)		
LPS Self Control Score (n=45, 20)	9.10 (± 10.73)	10.44 (± 10.42)		
LPS Total Score (n=45, 20)	10.67 (± 14.27)	12.64 (± 13.95)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Kiddie Sluggish Cognitive Tempo (K-SCT) at

Week 32 Endpoint

End point title	Change From Baseline in Kiddie Sluggish Cognitive Tempo (K-SCT) at Week 32 Endpoint
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End point description:

The K-SCT rating scale contains 3 components: Youth, Parent, and Teacher ratings. It queries 17 candidate SCT symptoms, such as daydreams, lost in a fog, sluggish/drowsy. Scores range from 0-51. Lower scores indicate less sluggish. APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF). Total Score-Parent Variation (n=45, 21)

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
Total Score-Parent Variation (n=45, 21)	-10.40 (± 11.94)	-10.83 (± 10.84)		
Total Score-Teacher Variation (n=23, 9)	-7.00 (± 12.82)	-7.89 (± 5.18)		
Total Score-Youth Variation (n=45, 21)	-4.36 (± 7.57)	-5.43 (± 8.44)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Multidimensional Self Concept Scale (MSCS) at Week 32 Endpoint

End point title	Change From Baseline in Multidimensional Self Concept Scale (MSCS) at Week 32 Endpoint
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End point description:

The MSCS is an overall assessment of self concept or an individual measure of any of the six scaled dimensions of self concept: Social, Competence, Affect, Academic, Family, and Physical. Standard scores range from 45-145. Higher scores are better (indicate higher self concept). APD: All randomized participants who entered open-label phase with a baseline and at least one post-baseline result, and last observation carried forward (LOCF).

End point type	Secondary
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End point timeframe:

Baseline, 32 weeks

End point values	ADHD+ Dyslexia (D): Atomoxetine	ADHD Alone: Atomoxetine		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	21		
Units: units on a scale				
arithmetic mean (standard deviation)				
Academic Standard Section Score	6.02 (± 9.72)	5.43 (± 6.98)		
Affect Standard Section Score	4.29 (± 11.14)	3.14 (± 10.45)		
Competence Standard Section Score	6.76 (± 11.77)	5.19 (± 7.94)		
Family Standard Section Score	0.16 (± 14.40)	0.33 (± 9.79)		
Physical Standard Section Score	6.09 (± 12.00)	2.43 (± 7.20)		
Social Standard Section Score	4.84 (± 11.84)	2.38 (± 11.75)		
Standard Total Score	5.61 (± 10.82)	3.48 (± 7.21)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

All randomized participants.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	13.1
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Reporting groups

Reporting group title	Placebo/Atomoxetine
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Reporting group description:

Participants were assigned to placebo in acute phase and Atomoxetine in open-label phase. Placebo was packaged in the same way as Atomoxetine, and administered orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with Atomoxetine.

Reporting group title	Atomoxetine/Atomoxetine
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Reporting group description:

Participants were assigned to Atomoxetine treatment in both acute and open-label phase. Atomoxetine was administered at 1.0 to 1.4 mg/kg/day given orally once daily in the morning for 16 weeks. All eligible participants who completed the double-blind acute phase had the option of participating in a 16-week open-label extension period in which participants were treated with atomoxetine.

Serious adverse events	Placebo/Atomoxetine	Atomoxetine/Atomoxetine	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 89 (0.00%)	1 / 120 (0.83%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Infections and infestations			
wound infection staphylococcal			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	0 / 89 (0.00%)	1 / 120 (0.83%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo/Atomoxetine	Atomoxetine/Atomoxetine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 89 (79.78%)	108 / 120 (90.00%)	
Investigations			
weight decreased			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	1 / 89 (1.12%)	6 / 120 (5.00%)	
occurrences (all)	1	6	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	5 / 89 (5.62%)	15 / 120 (12.50%)	
occurrences (all)	5	16	
headache			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	16 / 89 (17.98%)	27 / 120 (22.50%)	
occurrences (all)	21	36	
somnolence			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	0 / 89 (0.00%)	10 / 120 (8.33%)	
occurrences (all)	0	12	
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	9 / 89 (10.11%)	31 / 120 (25.83%)	
occurrences (all)	11	34	
irritability			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	8 / 89 (8.99%)	14 / 120 (11.67%)	
occurrences (all)	11	15	
pyrexia			
alternative dictionary used: MedDRA 13.1			
subjects affected / exposed	6 / 89 (6.74%)	2 / 120 (1.67%)	
occurrences (all)	6	3	
therapeutic response unexpected			

alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all)	2 / 89 (2.25%) 2	6 / 120 (5.00%) 12	
Gastrointestinal disorders abdominal discomfort alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all) abdominal pain upper alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all) diarrhoea alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all) nausea alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all) vomiting alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all)	2 / 89 (2.25%) 2 6 / 89 (6.74%) 8 3 / 89 (3.37%) 3 5 / 89 (5.62%) 6 8 / 89 (8.99%) 9	7 / 120 (5.83%) 8 23 / 120 (19.17%) 31 7 / 120 (5.83%) 7 34 / 120 (28.33%) 42 16 / 120 (13.33%) 24	
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all) oropharyngeal pain alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all)	8 / 89 (8.99%) 8 6 / 89 (6.74%) 6	6 / 120 (5.00%) 6 6 / 120 (5.00%) 6	
Skin and subcutaneous tissue disorders			

rash alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all)	6 / 89 (6.74%) 6	6 / 120 (5.00%) 6	
Psychiatric disorders aggression alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all)	0 / 89 (0.00%) 0	6 / 120 (5.00%) 6	
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 13.1 subjects affected / exposed occurrences (all)	4 / 89 (4.49%) 5	22 / 120 (18.33%) 22	

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