Clinical trial results:
A Multicenter, 10-Week, Randomized, Double-Blind Study Of Sertraline And Placebo In Children And Adolescents With Posttraumatic Stress Disorder (PTSD)

Summary

EudraCT number	2014-004162-17
Trial protocol	Outside EU/EEA
Global end of trial date	18 July 2007

Results information

Result version number	v1
This version publication date	03 June 2016
First version publication date	29 July 2015

Trial information

Trial identification

Sponsor protocol code	A0501061

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00150306
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, ClinicalTrials.govCallCenter@pfizer.com
Scientific contact	Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, ClinicalTrials.govCallCenter@pfizer.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	29 May 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 July 2007
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and efficacy of sertraline compared to placebo in children and adolescents (6 to 17 years of age) who are outpatients with the diagnosis of Posttraumatic Stress Disorder (PTSD).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 November 2002
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: 129
Worldwide total number of subjects	129
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)	74
Adolescents (12-17 years)	55
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in United States at 30 centers. The study started on 15 November 2002 and completed on 18 July 2007.

Pre-assignment

Screening details:

A total 204 subjects were screened, 131 subjects were assigned to treatment and 129 subjects received treatment.

Period 1

Period 1 title	Overall Study (overall period)
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	Sertraline

Arm description:

Subjects received daily 25 milligram (mg) dose of sertraline once daily. The 25 mg dose was maintained until the end of Week 1 visit. At that visit, the dose was increased to 50 mg daily and maintained at this level until the end of week 3 visit. Thereafter, it was permissible for dose increases to be made in 50 mg increments for 2-week intervals up to a maximum of 200 mg daily, based on clinical response and in the absence of dose-limiting adverse events (AEs).

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

Dosage and administration details:

Subjects received daily 25 mg dose of sertraline once daily. The 25-mg dose was maintained until the end of Week 1 visit. At that visit, the dose was increased to 50 mg daily and maintained at this level until the end of Week 3 visit. Thereafter, it was permissible for dose increases to be made in 50 mg increments for 2-week intervals up to a maximum of 200 mg daily, based on clinical response and in the absence of dose-limiting AEs.

Arm title	Placebo

Arm description:

Subjects received matching placebo once daily for 10 weeks.

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

Dosage and administration details:

Subjects received matching placebo once daily for 10 weeks.

Number of subjects in period 1	Sertraline	Placebo
Started	67	62
Completed	47	51
Not completed	20	11
Adverse Event	5	2
Other	6	3
Lost to follow-up	8	5
Lack of efficacy	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Sertraline
Reporting group description:	
Subjects received daily 25 milligram (mg) dose of sertraline once daily. The 25 mg dose was maintained until the end of Week 1 visit. At that visit, the dose was increased to 50 mg daily and maintained at this level until the end of week 3 visit. Thereafter, it was permissible for dose increases to be made in 50 mg increments for 2-week intervals up to a maximum of 200 mg daily, based on clinical response and in the absence of dose-limiting adverse events (AEs).	
Reporting group title	Placebo
Reporting group description:	
Subjects received matching placebo once daily for 10 weeks.	

Reporting group values	Sertraline	Placebo	Total
Number of subjects	67	62	129
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	10.8	11.2	
standard deviation	± 3.2	± 3.6	-
Gender categorical			
Units: Subjects			
Female	40	38	78
Male	27	24	51
UCLA PTSD-I Total Symptom Score at Baseline			
The UCLA PTSD-I was clinician -rated scale that consists of 22 items.The scale score for each item from 0 to 4,giving a possible score range of 0--68,with higher value indicating more frequency of symptoms. ITT population for efficacy analysis included those safety evaluable subjects who had baseline and post-randomization efficacy data. Safety evaluable subjects were defined as subjects who took atleast 1 dose of study drug and provided any follow up inforamtion.Number of subjects evaluable for UCLA PTSD-I Total Symptom Score at Baseline for sertraline and placebo was 63 and 54,respectively.			
Units: units on a scale			
arithmetic mean	43.5	41.6	
standard deviation	± 8.5	± 8.9	-

End points

End points reporting groups

Reporting group title	Sertraline

Reporting group description:

Subjects received daily 25 milligram (mg) dose of sertraline once daily. The 25 mg dose was maintained until the end of Week 1 visit. At that visit, the dose was increased to 50 mg daily and maintained at this level until the end of week 3 visit. Thereafter, it was permissible for dose increases to be made in 50 mg increments for 2-week intervals up to a maximum of 200 mg daily, based on clinical response and in the absence of dose-limiting adverse events (AEs).

Reporting group title	Placebo

Reporting group description:

Subjects received matching placebo once daily for 10 weeks.

Primary: Change From Baseline in the University of California at Los Angeles Post-Traumatic Stress Disorder Index (UCLA PTSD-I) for Diagnostic and Statistical Manual- IV (DSM-IV) Total Symptom Score at Endpoint

End point title	Change From Baseline in the University of California at Los Angeles Post-Traumatic Stress Disorder Index (UCLA PTSD-I) for Diagnostic and Statistical Manual- IV (DSM-IV) Total Symptom Score at Endpoint

End point description:

The UCLA PTSD-I was a clinician-rated scale that consists of 22 items. It assesses, in a direct, semistructured interview, the frequency of symptoms of PTSD as well as associated features. Each item was scored on a 5-point Likert scale (none, little, some, much, and most of the time) and the total symptom score was computed from 17 PTSD symptom frequency items. The scale score for each item from 0 to 4, giving a possible score range of 0-68, with higher value indicating more frequency of symptoms. Intent-to-treat (ITT) subject population for efficacy analysis included those safety evaluable subjects who had baseline and post-randomization efficacy data. Safety evaluable subjects were defined as subjects who took atleast 1 dose of study drug and provided any follow up inforamtion.

End point type	Primary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	63	54		
Units: Units on a scale				
least squares mean (standard error)	-17 (± 2.1)	-20.3 (± 2.4)		

Statistical analyses

Statistical analysis title	UCLA PTSD-I Total Symptom Score at endpoint

Statistical analysis description:

Analyses were based on ANOVA with model terms of treatment group, age strata, and center for endpoint.

Comparison groups	Sertraline v Placebo

Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.212
Method	ANOVA

Secondary: Change From Baseline in University of California at Los Angeles Post-Traumatic Stress Disorder Index (UCLA PTSD-I) Symptom Cluster Scores at Endpoint

End point title	Change From Baseline in University of California at Los Angeles Post-Traumatic Stress Disorder Index (UCLA PTSD-I) Symptom Cluster Scores at Endpoint

End point description:

UCLA PTSD-RI symptom clusters of re-experiencing, avoidance, and increased arousal;as well as associated features sub-factor score. Symptom cluster of re-experiencing:sum of individual items 2, 3, 5, 6, 18; score range=0-20, higher value=more re-experiencing.Symptom cluster of avoidance for children:sum of individual items 7, 8, 9, 15, 17, 19a,higher score from items 10 or 11.For adolescents, item 19a score was replaced by the higher of items 19a or 19b;score range=0-28,higher value=more avoidance.Symptom cluster of increased arousal for children:sum of individual items 1, 4a, 12, 13, 16.For adolescents, item 4a was replaced by the higher of items 4a or 4b; score range=0-20,higher score=increased arousal. Associated feature sub-factor score was sum of items 14 and 20;score range=0-8, higher score=worsening. The interim analysis showed that sertraline was unlikely to separate from placebo at study end.The study was terminated early, and only safety and primary parameter were analyzed.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[1]	0[2]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[1] - The study was terminated hence data was not analyzed.

[2] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in University of California at Los Angeles Post-Traumatic Stress Disorder Index (UCLA PTSD-I) Individual Item Scores at Endpoint

End point title	Change From Baseline in University of California at Los Angeles Post-Traumatic Stress Disorder Index (UCLA PTSD-I) Individual Item Scores at Endpoint

End point description:

The UCLA PTSD-I was a clinician-rated scale that consists of 22 items. It assesses, in a direct, semistructured interview, the frequency of symptoms of PTSD as well as associated features. Each item was scored on a 5-point Likert scale (none, little, some, much, and most of the time) The individual item score ranges from 0-4, with higher indicating long duration of symptom. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to

terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[3]	0[4]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[3] - The study was terminated hence data was not analyzed.

[4] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Basleine in the Total Endorsed Symptom Score and Total Endorsed Cluster Symptom Score at Endpoint

End point title	Change From Basleine in the Total Endorsed Symptom Score and Total Endorsed Cluster Symptom Score at Endpoint

End point description:

The total endorsed symptom score was defined as sum of UCLA PTSD-I individual items with a score of either 3 (much time) or 4 (most time) for each subject at baseline and endpoint. The score ranges from 0-57 or 0-68, with higher value indicating long duration of symptoms. The total endorsed re-experiencing symptom score, total endorsed avoidance symptom score, and total endorsed increased arousal symptom score. The total endorsed cluster symptom score was defined as sum of UCLA PTSD-RI individual items with a score of either 3 (much time) or 4 (most time) within that symptom cluster for each subject at baseline and endpoint. The score ranges from 0-57 or 0-68, with higher value indicating more clustered symptoms. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[5]	0[6]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[5] - The study was terminated hence data was not analyzed.

[6] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Child Stress Disorder Checklist (CSDC) Total Score and Symptom Clusters at Endpoint

End point title	Change From Baseline in the Child Stress Disorder Checklist (CSDC) Total Score and Symptom Clusters at Endpoint

End point description:

The CSDC was a 30-item parent/guardian-rated scale that evaluates PTSD symptoms and functional impairment. CSDC total score and symptom clusters of: re-experiencing symptom cluster which was to be calculated as the sum of items 1, 3, 12, 19, 22, 23, and 25; avoidance symptom cluster was calculated as the sum of items 5, 14, 21, 28, and 30; numbing and dissociation symptom cluster was calculated as the sum of items 4, 7, 9, 16, 18, 20, 26, and 27; increased arousal symptom cluster was calculated as the sum of items 2, 6, 8, 13, 17, and 29; as well as sub-factor score of impairment in function were calculated as the sum of items 10, 11, 15, and 24. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were anayzed and reported.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[7]	0[8]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[7] - The study was terminated hence data was not analyzed.

[8] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Child Stress Disorder Checklist (CSDC) Individual Item Scores at Endpoint

End point title	Change From Baseline in Child Stress Disorder Checklist (CSDC) Individual Item Scores at Endpoint

End point description:

The CSDC was a 30-item parent/guardian-rated scale that evaluates PTSD symptoms and functional impairment. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were anayzed and reported.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[9]	0[10]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[9] - The study was terminated hence data was not analyzed.

[10] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Clinical Global Impression Severity of Illness (CGI-S) Score at Endpoint

End point title	Change From Baseline in the Clinical Global Impression Severity of Illness (CGI-S) Score at Endpoint

End point description:

The CGI-S scale are clinician-rated measures that assess the subject's severity of illness . For CGI-S, the investigator was to rate the subject in response to the following question:"Considering your total clinical experience with PTSD, how mentally ill is the subject at this time?" The ratings were: 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; and 7 = among the most extremely ill. The CGI-S scale score ranges from 0 to 7, with higher value indicating no improvement or more severe illness condition. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[11]	0[12]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[11] - The study was terminated hence data was not analyzed.

[12] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Global Impression Improvement (CGI-I) scores at the Endpoint

End point title	Clinical Global Impression Improvement (CGI-I) scores at the Endpoint

End point description:

The CGI-I scales are clinician-rated measures that assess the subject's ill global improvement, respectively. For CGI-I, the investigator was to rate the subject in response to the following question:"Compared to the subject's condition at Baseline, how much has he/she changed?" He or she was to rate the global improvement whether or not, in his or her judgment, it was due entirely to drug treatment. The ratings were: 1= very much improved; 2= much improved; 3= minimally improved; 4= no change; 5= minimally worse; 6= much worse; and 7= very much worse. The CGI-I scale score

ranges from 0 to 7, with higher value indicating no improvement or more worse condition. The interim analysis showed that sertraline
treatment was unlikely to separate from placebo at end of study it was decided to terminate the study e arly, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[13]	0[14]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[13] - The study was terminated hence data was not analyzed.

[14] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Responders Based on Clinical Global Impression Improvement (CGI-I) Scores at Endpoint

End point title	Percentage of Responders Based on Clinical Global Impression Improvement (CGI-I) Scores at Endpoint

End point description:

Responders: percentage of subjects with CGI-I ≤ 2 (“very much” or “much” improved) at endpoint. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Endpoint (End of Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[15]	0[16]		
Units: Percentage of subjects				
number (not applicable)				

Notes:

[15] - The study was terminated hence data was not analyzed.

[16] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Remitters Based on the Kiddie Schedule for Affective

Disorders and Schizophrenia for School-Age Children - Present and Lifetime Version (K-SADS-PL) at Endpoint

End point title	Percentage of Remitters Based on the Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children - Present and Lifetime Version (K-SADS-PL) at Endpoint

End point description:

K-SADS-PL as the diagnostic interview was used to assesses the presence of symptoms of PTSD, as well as other psychiatric disorders, on the basis of DSM-IV diagnostic criteria. Remitters: percentage of subjects who no longer meet criteria for the diagnosis of PTSD as assessed by the K-SADS-PL at endpoint. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Endpoint (End of Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[17]	0[18]		
Units: Percentage of subjects				
number (not applicable)				

Notes:

[17] - The study was terminated hence data was not analyzed.

[18] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Investigator Rated Children's Depression Rating Scale Revised (CDRS-R) Total Score at Endpoint

End point title	Change From Baseline in the Investigator Rated Children's Depression Rating Scale Revised (CDRS-R) Total Score at Endpoint

End point description:

The CDRS-R was a clinician-rated scale that consists of 17 items and assesses the severity of symptoms of depression. The first 14 items were symptom ratings and the remaining 3 items were rated on the basis of the subject's nonverbal behavior (i.e., depressed facial affect, listless speech, hypoactivity). The 17 items of the CDRS-R were scored from 1 to 5 for sleep disturbance, appetite disturbance and listless speech items, and from 1 to 7 for the remaining 14 items. The CDRS-R score ranges from 0 to 113, with higher score range indicating more severe symptom of depression. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[19]	0[20]		
Units: Units on a scale				
least squares mean (standard error)	()	()		

Notes:

[19] - The study was terminated hence data was not analyzed.

[20] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Total Score at Endpoint

End point title	Change From Baseline in the Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Total Score at Endpoint

End point description:

The PQ-LES-Q was a self-report measure that assesses the quality of life in children and adolescents. It was derived from the adult version of the scale, the Quality of Life Enjoyment and Satisfaction Questionnaire and has been reworded to capture events more relevant to a child or adolescent. The 15 items of the scale were rated on a scale of: 1= very poor; 2= poor; 3= fair; 4= good; 5= very good. The PQ-LES-Q score ranges from 0-75, with higher score indicating better quality of life. The interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

End point type	Secondary

End point timeframe:

Baseline, Endpoint (last assessment for a subject up to Week 10)

End point values	Sertraline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[21]	0[22]		
Units: Units on a scale				
arithmetic mean (standard deviation)	()	()		

Notes:

[21] - The study was terminated hence data was not analyzed.

[22] - The study was terminated hence data was not analyzed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment emergent adverse events are reported from time of first dose of study treatment up to 7 days after last dose of study treatment

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Sertraline

Reporting group description:

Subjects received daily 25 mg dose of sertraline once daily. The 25 mg dose was maintained until the end of Week 1 visit. At that visit, the dose was increased to 50 mg daily and maintained at this level until the end of Week 3 visit. Thereafter, it was permissible for dose increases to be made in 50 mg increments for 2-week intervals up to a maximum of 200 mg daily, based on clinical response and in the absence of dose-limiting AEs.

Reporting group title	Placebo

Reporting group description:

Subjects received matching placebo once daily for 10 weeks.

Serious adverse events	Sertraline	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 67 (2.99%)	0 / 62 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Psychomotor hyperactivity			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion disorder			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Suicidal ideation			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Varicella			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Sertraline	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	51 / 67 (76.12%)	47 / 62 (75.81%)	
General disorders and administration site conditions			
Crying			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Fatigue			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	3 / 67 (4.48%)	2 / 62 (3.23%)	
occurrences (all)	4	2	
Thirst			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 67 (1.49%)	2 / 62 (3.23%)	
occurrences (all)	1	3	
Reproductive system and breast disorders			
Breast pain			

subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Dysmenorrhoea			
subjects affected / exposed	0 / 67 (0.00%)	2 / 62 (3.23%)	
occurrences (all)	0	4	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 67 (1.49%)	2 / 62 (3.23%)	
occurrences (all)	1	2	
Cough			
subjects affected / exposed	4 / 67 (5.97%)	0 / 62 (0.00%)	
occurrences (all)	5	0	
Nasal congestion			
subjects affected / exposed	2 / 67 (2.99%)	1 / 62 (1.61%)	
occurrences (all)	2	1	
Oropharyngeal pain			
subjects affected / exposed	4 / 67 (5.97%)	2 / 62 (3.23%)	
occurrences (all)	4	2	
Rhinitis allergic			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea			
subjects affected / exposed	2 / 67 (2.99%)	0 / 62 (0.00%)	
occurrences (all)	2	0	
Sinus congestion			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Throat irritation			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Tonsillar hypertrophy			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Upper respiratory tract congestion			

subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Agitation			
subjects affected / exposed	2 / 67 (2.99%)	2 / 62 (3.23%)	
occurrences (all)	2	2	
Anxiety			
subjects affected / exposed	2 / 67 (2.99%)	1 / 62 (1.61%)	
occurrences (all)	2	1	
Attention deficit/hyperactivity disorder			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Encopresis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Hallucination, visual			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Impulsive behaviour			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	7 / 67 (10.45%)	8 / 62 (12.90%)	
occurrences (all)	9	9	
Irritability			
subjects affected / exposed	1 / 67 (1.49%)	1 / 62 (1.61%)	
occurrences (all)	1	1	
Mood altered			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Mood swings			

subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Morose			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Nervousness			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Nightmare			
subjects affected / exposed	0 / 67 (0.00%)	2 / 62 (3.23%)	
occurrences (all)	0	2	
Panic attack			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Self injurious behaviour			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Suicidal ideation			
subjects affected / exposed	2 / 67 (2.99%)	0 / 62 (0.00%)	
occurrences (all)	2	0	
Tearfulness			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Tic			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Heart rate decreased			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Red blood cell morphology abnormal			
subjects affected / exposed	1 / 67 (1.49%)	1 / 62 (1.61%)	
occurrences (all)	1	1	

Weight decreased			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Burns second degree			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Contusion			
subjects affected / exposed	3 / 67 (4.48%)	1 / 62 (1.61%)	
occurrences (all)	3	1	
Fall			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Foot fracture			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Laceration			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Ligament sprain			
subjects affected / exposed	2 / 67 (2.99%)	3 / 62 (4.84%)	
occurrences (all)	2	3	
Limb injury			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Skin abrasion			
subjects affected / exposed	1 / 67 (1.49%)	1 / 62 (1.61%)	
occurrences (all)	1	1	
Torus fracture			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			

Bradycardia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Palpitations			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Convulsion			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Disturbance in attention			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	3 / 67 (4.48%)	5 / 62 (8.06%)	
occurrences (all)	3	6	
Headache			
subjects affected / exposed	17 / 67 (25.37%)	12 / 62 (19.35%)	
occurrences (all)	22	12	
Loss of consciousness			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Migraine			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Psychomotor hyperactivity			
subjects affected / exposed	6 / 67 (8.96%)	1 / 62 (1.61%)	
occurrences (all)	7	1	
Somnolence			

subjects affected / exposed	3 / 67 (4.48%)	0 / 62 (0.00%)	
occurrences (all)	3	0	
Speech disorder			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Hypochromasia			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Lymphadenitis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Macrocytosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Microcytosis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Ear canal erythema			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Ear congestion			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Ear discomfort			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Ear pain			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 67 (1.49%)	1 / 62 (1.61%)	
occurrences (all)	3	1	
Abdominal pain			

subjects affected / exposed	1 / 67 (1.49%)	1 / 62 (1.61%)	
occurrences (all)	2	1	
Abdominal pain upper			
subjects affected / exposed	8 / 67 (11.94%)	10 / 62 (16.13%)	
occurrences (all)	10	12	
Abdominal tenderness			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	2 / 67 (2.99%)	0 / 62 (0.00%)	
occurrences (all)	2	0	
Diarrhoea			
subjects affected / exposed	6 / 67 (8.96%)	3 / 62 (4.84%)	
occurrences (all)	6	3	
Dry mouth			
subjects affected / exposed	5 / 67 (7.46%)	0 / 62 (0.00%)	
occurrences (all)	5	0	
Flatulence			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	9 / 67 (13.43%)	6 / 62 (9.68%)	
occurrences (all)	11	8	
Toothache			
subjects affected / exposed	3 / 67 (4.48%)	1 / 62 (1.61%)	
occurrences (all)	3	1	
Vomiting			
subjects affected / exposed	9 / 67 (13.43%)	3 / 62 (4.84%)	
occurrences (all)	10	3	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	

Blister			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Dry skin			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Ecchymosis			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Rash papular			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Swelling face			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Enuresis			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Haematuria			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 67 (0.00%)	2 / 62 (3.23%)	
occurrences (all)	0	3	
Back pain			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Myalgia			
subjects affected / exposed	1 / 67 (1.49%)	1 / 62 (1.61%)	
occurrences (all)	1	4	
Pain in extremity			

subjects affected / exposed	0 / 67 (0.00%)	2 / 62 (3.23%)	
occurrences (all)	0	2	
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	1 / 67 (1.49%)	2 / 62 (3.23%)	
occurrences (all)	1	2	
Gastroenteritis viral			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Influenza			
subjects affected / exposed	3 / 67 (4.48%)	2 / 62 (3.23%)	
occurrences (all)	3	2	
Localised infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	2 / 67 (2.99%)	5 / 62 (8.06%)	
occurrences (all)	3	7	
Otitis externa			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Otitis media			
subjects affected / exposed	1 / 67 (1.49%)	2 / 62 (3.23%)	
occurrences (all)	1	2	
Otitis media acute			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Paronychia			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Pharyngitis streptococcal			
subjects affected / exposed	2 / 67 (2.99%)	0 / 62 (0.00%)	
occurrences (all)	2	0	
Respiratory tract infection			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	

Sinusitis			
subjects affected / exposed	3 / 67 (4.48%)	1 / 62 (1.61%)	
occurrences (all)	3	1	
Tinea infection			
subjects affected / exposed	0 / 67 (0.00%)	1 / 62 (1.61%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	4 / 67 (5.97%)	3 / 62 (4.84%)	
occurrences (all)	4	3	
Urinary tract infection			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	2 / 67 (2.99%)	0 / 62 (0.00%)	
occurrences (all)	2	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 67 (4.48%)	2 / 62 (3.23%)	
occurrences (all)	3	2	
Increased appetite			
subjects affected / exposed	1 / 67 (1.49%)	0 / 62 (0.00%)	
occurrences (all)	1	0	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Since the interim analysis showed that sertraline treatment was unlikely to separate from placebo at end of study it was decided to terminate the study early, and only safety and the primary efficacy parameter were analyzed and reported.

Notes: