# 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: