



Clinical trial results:

Prevalence of depression, anxiety and impulse control disorder (ICD) in patients with Parkinson's disease and effectiveness of escitalopram

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2007-004009-93 |
| Trial protocol | IT |
| Global end of trial date | 23 July 2010 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 05 January 2017 |
| First version publication date | 05 January 2017 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 12118A |
|-----------------------|--------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Lundbeck Italy |
| Sponsor organisation address | Via della Moscova 3, Milano , Italy, 20121 |
| Public contact | LundbeckClinicalTrials@lundbeck.com, LUNDBECK ITALIA SpA, LundbeckClinicalTrials@lundbeck.com |
| Scientific contact | LundbeckClinicalTrials@lundbeck.com, LUNDBECK ITALIA SpA, LundbeckClinicalTrials@lundbeck.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? | No |

Notes:

Results analysis stage

| | |
|--|--------------|
| Analysis stage | Final |
| Date of interim/final analysis | 23 July 2010 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 23 July 2010 |
| Global end of trial reached? | Yes |
| Global end of trial date | 23 July 2010 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the present study is to evaluate the efficacy and safety of escitalopram 10-20 mg/day in depression, anxiety or impulse control disorder (ICD) symptoms in patients suffering from Parkinson disease (efficacy objective)

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki and ICH Good Clinical Practice

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 27 November 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 | Italy: 14 |
| Worldwide total number of subjects | 14 |
| EEA total number of subjects | 14 |

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) | 0 |
| Adults (18-64 years) | 8 |
| From 65 to 84 years | 6 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects who met each of the inclusion and none of the exclusion criteria were eligible to participate in the study

Period 1

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

Arms

| | |
|------------------------------|---|
| Are arms mutually exclusive? | Yes |
| Arm title | Parkinson patients with depression symptoms |

Arm description:

Study duration per patient was 6 months as per treatment period.

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

Dosage and administration details:

Starting dose: 5 mg/day for 1 week. Dose adjustment was allowed starting from the first visit (1.5 month after treatment start) with possible increase up to 20 mg/day according to clinical needs. Flexible doses 10-20 mg/day were allowed from visit 1 to the end of treatment.

| | |
|------------------|--|
| Arm title | Parkinson patients with anxiety symptoms |
|------------------|--|

Arm description:

Study duration per patient was 6 months as per treatment period.

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

Dosage and administration details:

Starting dose: 5 mg/day for 1 week. Dose adjustment was allowed starting from the first visit (1.5 month after treatment start) with possible increase up to 20 mg/day according to clinical needs. Flexible doses 10-20 mg/day were allowed from visit 1 to the end of treatment.

| | |
|------------------|--|
| Arm title | Parkinson patients with impulse control symptoms |
|------------------|--|

Arm description:

Study duration per patient was 6 months as per treatment period.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--------------|
| Investigational medicinal product name | Escitalopram |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Starting dose: 5 mg/day for 1 week. Dose adjustment was allowed starting from the first visit (1.5 month after treatment start) with possible increase up to 20 mg/day according to clinical needs. Flexible doses 10-20 mg/day were allowed from visit 1 to the end of treatment.

| Number of subjects in period 1 | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control symptoms |
|---------------------------------------|---|--|--|
| Started | 2 | 2 | 10 |
| Completed | 0 | 2 | 5 |
| Not completed | 2 | 0 | 5 |
| Adverse event, non-fatal | 1 | - | 3 |
| Lost to follow-up | 1 | - | 2 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|---------------|
| Reporting group title | Overall Trial |
| Reporting group description: - | |

| Reporting group values | Overall Trial | Total | |
|--|---------------|-------|--|
| Number of subjects | 14 | 14 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 8 | 8 | |
| From 65-84 years | 6 | 6 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 62.1 | | |
| standard deviation | ± 8 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 5 | 5 | |
| Male | 9 | 9 | |
| Race | | | |
| Units: Subjects | | | |
| Caucasian | 14 | 14 | |

Subject analysis sets

| | |
|--|---|
| Subject analysis set title | Parkinson patients with depression symptoms |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Depression symptoms in patients suffering from Parkinson disease | |
| Subject analysis set title | Parkinson patients with anxiety symptoms |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Anxiety symptoms in patients suffering from Parkinson disease | |
| Subject analysis set title | Parkinson patients with impulse control disorder symptoms |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| impulse control disorder (ICD) symptoms in patients suffering from Parkinson disease | |

| Reporting group values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms |
|--|---|--|---|
| Number of subjects | 2 | 2 | 10 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 1 | 0 | 7 |
| From 65-84 years | 1 | 2 | 3 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 66.5 | 71 | 59.4 |
| standard deviation | ± 9.2 | ± 7.1 | ± 6.9 |
| Gender categorical Units: Subjects | | | |
| Female | 1 | 2 | 2 |
| Male | 1 | 0 | 8 |
| Race Units: Subjects | | | |
| Caucasian | 2 | 2 | 10 |

End points

End points reporting groups

| | |
|--|---|
| Reporting group title | Parkinson patients with depression symptoms |
| Reporting group description: | |
| Study duration per patient was 6 months as per treatment period. | |
| Reporting group title | Parkinson patients with anxiety symptoms |
| Reporting group description: | |
| Study duration per patient was 6 months as per treatment period. | |
| Reporting group title | Parkinson patients with impulse control symptoms |
| Reporting group description: | |
| Study duration per patient was 6 months as per treatment period. | |
| Subject analysis set title | Parkinson patients with depression symptoms |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Depression symptoms in patients suffering from Parkinson disease | |
| Subject analysis set title | Parkinson patients with anxiety symptoms |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Anxiety symptoms in patients suffering from Parkinson disease | |
| Subject analysis set title | Parkinson patients with impulse control disorder symptoms |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| impulse control disorder (ICD) symptoms in patients suffering from Parkinson disease | |

Primary: Change from baseline in Hamilton Rating Scale for Depression (HAM-D) score

| | |
|------------------------------|---|
| End point title | Change from baseline in Hamilton Rating Scale for Depression (HAM-D) score ^[1] |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| baseline to end of treatment | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive statistics

| End point values | Parkinson patients with depression symptoms | Parkinson patients with impulse control disorder symptoms | | |
|--------------------------------------|---|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2 | 4 | | |
| Units: Score | | | | |
| arithmetic mean (standard deviation) | -2.5 (± 3.5) | 2 (± 6) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in Hamilton Rating Scale for Anxiety (HAM-A) score

| | |
|-----------------|--|
| End point title | Change from baseline in Hamilton Rating Scale for Anxiety (HAM-A) score ^[2] |
|-----------------|--|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:
baseline to end of treatment

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive statistics

| End point values | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | | |
|--------------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2 | 5 | | |
| Units: score | | | | |
| arithmetic mean (standard deviation) | -8 (± 5.7) | -1.4 (± 7.1) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in Barrat Impulsivness Scale (BIS) total score

| | |
|-----------------|--|
| End point title | Change from baseline in Barrat Impulsivness Scale (BIS) total score ^[3] |
|-----------------|--|

End point description:

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:
baseline to end of treatment

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive statistics

| End point values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | |
|--------------------------------------|---|--|---|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 2 | 2 | 7 | |
| Units: Score | | | | |
| arithmetic mean (standard deviation) | 18 (± 41) | 2.5 (± 20.5) | 5.6 (± 14) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Unified Parkinson Disease Rating Scale (UPDRS) total score

| | |
|-----------------|--|
| End point title | Change from baseline in Unified Parkinson Disease Rating Scale (UPDRS) total score |
|-----------------|--|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

baseline to end of treatment

| End point values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | |
|--------------------------------------|---|--|---|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 2 | 2 | 7 | |
| Units: Scale | | | | |
| arithmetic mean (standard deviation) | 5 (\pm 7.1) | -8.5 (\pm 12) | -0.3 (\pm 3.8) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Visual Analogic Scale (VAS) for daily off time.

| | |
|-----------------|---|
| End point title | Change from baseline in Visual Analogic Scale (VAS) for daily off time. |
|-----------------|---|

End point description:

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline to end of treatment

| End point values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | |
|--------------------------------------|---|--|---|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 1 | 2 | 7 | |
| Units: Scale | | | | |
| arithmetic mean (standard deviation) | 9 (± 0) | -0.2 (± 0.2) | -0.6 (± 1.2) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in UPDRS-II (ADL)

| | |
|--|--|
| End point title | Change from baseline in UPDRS-II (ADL) |
| End point description: Unified Parkinson Disease Rating Scale (UPDRS) | |
| End point type | Secondary |
| End point timeframe: baseline to end of treatment | |

| End point values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | |
|--------------------------------------|---|--|---|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 2 | 2 | 7 | |
| Units: Scores | | | | |
| arithmetic mean (standard deviation) | 2.5 (± 3.5) | -1.5 (± 3.5) | -1.1 (± 3.1) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Parkinson Disease Questionnaire 39 (PDQ-39)

| | |
|--|---|
| End point title | Change from baseline in Parkinson Disease Questionnaire 39 (PDQ-39) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: baseline to end of treatment | |

| End point values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | |
|--------------------------------------|---|--|---|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 2 | 2 | 7 | |
| Units: Score | | | | |
| arithmetic mean (standard deviation) | 25 (± 17) | -26.5 (± 12) | -12 (± 14.6) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in BDI; depression self evaluation

| | |
|---|---|
| End point title | Change from baseline in BDI; depression self evaluation |
| End point description: Beck Depression Inventory (BDI); depression self evaluation | |
| End point type | Secondary |
| End point timeframe: baseline to end of treatment | |

| End point values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | |
|--------------------------------------|---|--|---|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 2 | 2 | 7 | |
| Units: Score | | | | |
| arithmetic mean (standard deviation) | 3 (± 11.3) | -3 (± 9.9) | -2.1 (± 2.9) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Symptom Check List-90 (SCL-90) compulsive behaviour – self evaluation

| | |
|---|---|
| End point title | Change from baseline in Symptom Check List-90 (SCL-90) compulsive behaviour – self evaluation |
| End point description: Symptom Check List-90 (SCL-90); compulsive behavior – self evaluation | |
| End point type | Secondary |

End point timeframe:
baseline to end of treatment

| End point values | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms | |
|--------------------------------------|---|--|---|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 2 | 2 | 7 | |
| Units: Score | | | | |
| arithmetic mean (standard deviation) | 51 (± 17) | -61 (± 8.5) | -16.7 (± 30.7) | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline to end of treatment

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 16.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---|
| Reporting group title | Parkinson patients with depression symptoms |
|-----------------------|---|

Reporting group description: -

| | |
|-----------------------|--|
| Reporting group title | Parkinson patients with anxiety symptoms |
|-----------------------|--|

Reporting group description: -

| | |
|-----------------------|---|
| Reporting group title | Parkinson patients with impulse control disorder symptoms |
|-----------------------|---|

Reporting group description: -

| Serious adverse events | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms |
|---|---|--|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 10 (10.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Cardiac disorders | | | |
| severe pericarditis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Parkinson patients with depression symptoms | Parkinson patients with anxiety symptoms | Parkinson patients with impulse control disorder symptoms |
|---|---|--|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 2 (0.00%) | 4 / 10 (40.00%) |
| Nervous system disorders | | | |
| On and Off phenomenon | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 2 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Vertigo | | | |

| | | | |
|---|---------------------|--------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 2 (0.00%) 0 | 1 / 10 (10.00%) 1 |
| Psychiatric disorders Anxiety aggravated subjects affected / exposed occurrences (all) | 1 / 2 (50.00%) 1 | 0 / 2 (0.00%) 0 | 1 / 10 (10.00%) 1 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 13 September 2007 | <ul style="list-style-type: none">-New title-The Padua Inventory (PI) was been replaced by the Barrat Impulsiveness Scale (BIS) as primary efficacy parameter for ICD diagnostic group- The PI has been replaced by BIS in the following paragraphes of the protocol-The MINI structured interview has been introduced for diagnosis to be made |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|--------------|--|--------------|
| 23 July 2010 | it was decided to stop enrolment for this study, because of enrolment difficulties at site. Planned sample size was more than 200 patients | - |

Notes:

Limitations and caveats

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

The study was terminated and no meaningful interpretations can be made. Planned sample size was more than 200 patients

Notes: