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 (± 7.1)	-8.5 (± 12)	-0.3 (± 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 witn 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 witn 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 witn 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	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety aggravated			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 September 2007	-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: