



Clinical trial results:

LATE ONSET PARKINSON'S DISEASE IN SUBJECTS 70 YEARS AND OLDER: POSSIBLE USE OF ROTIGOTINE

Summary

EudraCT number	2013-000827-15
Trial protocol	IT
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	16 May 2021
First version publication date	16 May 2021

Trial information

Trial identification

Sponsor protocol code	PARROT
-----------------------	--------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Osp. Card. G. Panico
Sponsor organisation address	Via San Pio X n. 4, Tricase, Italy, 73039
Public contact	Elisabetta Pupillo, Istituto di Ricerche Farmacologiche "Mario Negri" di Milano, elisabetta.pupillo@marionegri.it
Scientific contact	Elisabetta Pupillo, Istituto di Ricerche Farmacologiche "Mario Negri" di Milano, elisabetta.pupillo@marionegri.it

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	Interim
Date of interim/final analysis	25 May 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	No
------------------------------	----

Notes:

General information about the trial

Main objective of the trial:

Primary objective: To assess efficacy and safety of rotigotine in patients with late onset PD, starting at age 70 or later, on motor symptoms.

Protection of trial subjects:

Safety monitoring for all patients enrolled in the study will include laboratory safety assessments and clinical evaluation, as scheduled in the flow chart. All adverse events (AE) and serious adverse events (SAE) will be recorded.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2013
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: 2
Worldwide total number of subjects	2
EEA total number of subjects	2

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)	0
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

70+y;Idiopathic PD confirmed by at least2of the following signs:resting tremor,bradikinesia,rigidity;Onset of PD symptoms and diagnosis within the last12months;Disease stage I or II according to H&Y scale;Ability to provide written IC Patients willing and able to comply with scheduled visits,treatment plan,lab tests and other study procedures

Pre-assignment period milestones

Number of subjects started	2
Number of subjects completed	2

Period 1

Period 1 title	overall trial (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	active

Arm description:

Treatment is titrated to optimal dose (that at which investigator and subject felt that motor and non motor impairment are adequately controlled), starting at 2 mg/24 hr and increasing with weekly increments of 2 mg/24 hr up to a maximum of 8 mg/24 hr. The dose is maintained at the optimal or maximal dose for a 8-week period (maintenance period) .

Arm type	Experimental
Investigational medicinal product name	Rotigotine
Investigational medicinal product code	Rotigotine
Other name	
Pharmaceutical forms	Transdermal patch
Routes of administration	Transdermal use

Dosage and administration details:

Treatment is titrated to optimal dose (that at which investigator and subject felt that motor and non motor impairment are adequately controlled), starting at 2 mg/24 hr and increasing with weekly increments of 2 mg/24 hr up to a maximum of 8 mg/24 hr. The dose is maintained at the optimal or maximal dose for a 8-week period (maintenance period) .

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Transdermal patch
Routes of administration	Transdermal use

Dosage and administration details:

placebo

Arm title	placebo
------------------	---------

Arm description:

placebo, transdermal patch

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Transdermal patch
Routes of administration	Transdermal use

Dosage and administration details:

placebo

Number of subjects in period 1	active	placebo
Started	1	1
Completed	1	1

Baseline characteristics

Reporting groups

Reporting group title	overall trial
-----------------------	---------------

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	2	2	
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)	0	0	
From 65-84 years	2	2	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	1	1	
Male	1	1	

End points

End points reporting groups

Reporting group title	active
Reporting group description: Treatment is titrated to optimal dose (that at which investigator and subject felt that motor and non motor impairment are adequately controlled), starting at 2 mg/24 hr and increasing with weekly increments of 2 mg/24 hr up to a maximum of 8 mg/24 hr. The dose is maintained at the optimal or maximal dose for a 8-week period (maintenance period) .	
Reporting group title	placebo
Reporting group description: placebo, transdermal patch	

Primary: safety

End point title	safety
End point description: To assess efficacy and safety of rotigotine in patients with late onset PD, starting at age 70 or later, on motor symptoms	
End point type	Primary
End point timeframe: from baseline to week 16	

End point values	active	placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: percentage	1	1		

Statistical analyses

Statistical analysis title	descriptive statistics
Statistical analysis description: descriptive statistics for the assessment of the comparability of the two treatment groups and the safety of active treatment and placebo, and the use of ad-hoc statistical tests (univariate and multivariate) for the efficacy analysis.	
Comparison groups	active v placebo
Number of subjects included in analysis	2
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Chi-squared

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

AE were reported during the treatment period

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

Dictionary used

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

Dictionary version	3
--------------------	---

Frequency threshold for reporting non-serious adverse events: 1 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: no adverse events recorded

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? Yes

Date	Interruption	Restart date
25 May 2015	slow recruitment, study closed prematurely	-

Notes:

Limitations and caveats

None reported