



Clinical trial results:

Single-centre open label exploratory phase IIb pilot study of exogenous oral Melatonin for the treatment of Nocturia in adults with Parkinson's disease

Summary

EudraCT number	2014-002697-37
Trial protocol	GB
Global end of trial date	07 December 2018

Results information

Result version number	v1 (current)
This version publication date	14 November 2020
First version publication date	14 November 2020

Trial information

Trial identification

Sponsor protocol code	14/0382
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02359448
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University College London
Sponsor organisation address	Gower Steet, London, United Kingdom,
Public contact	Joint Research Office, UCL, CTIMPS@ucl.ac.uk
Scientific contact	Joint Research Office, UCL, CTIMPS@ucl.ac.uk

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	07 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 December 2018
Global end of trial reached?	Yes
Global end of trial date	07 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the effects of melatonin on bother related to nocturia.

Protection of trial subjects:

Patients were closely monitored throughout the length of the clinical trial by members of the study team

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 March 2015
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 Kingdom: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

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)	13
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

We included over

18 year old patients reporting nocturia based on to NMSQuest item 9 –“Getting up regularly at night to pass urine” two or more times at night.

Period 1

Period 1 title	Main study period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Open label

Arms

Arm title	Melatonin
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Arm description:

Melatonin treatment arm

Arm type	Experimental
Investigational medicinal product name	Melatonin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Prolonged-release tablet
Routes of administration	Oral use

Dosage and administration details:

2mg

Number of subjects in period 1	Melatonin
Started	28
Completed	28

Baseline characteristics

End points

End points reporting groups

Reporting group title	Melatonin
Reporting group description:	
Melatonin treatment arm	

Primary: Improvement on bother related to nocturia, as measured by the International Consultation on Incontinence Questionnaire Nocturia Module (ICIQ-N).

End point title	Improvement on bother related to nocturia, as measured by the International Consultation on Incontinence Questionnaire Nocturia Module (ICIQ-N). ^[1]
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End point description:

End point type	Primary
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End point timeframe:

The primary outcome will be evaluated at the end of 6 weeks of Melatonin treatment (week 8 of the study).

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:

statistical analysis for ICIQ-N was non-parametric Wilcoxon signed-ranked test

End point values	Melatonin			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: 0-8				
number (not applicable)	21			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

during the course of the study

No serious adverse events reported

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
Dictionary version	4

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

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 were recorded during the trial due to the safety profile of the drug. The drug is a marketed product with low risk associated with it, therefore no SAE's were reported

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

None reported