



Clinical trial results:

Effects of different concentrations of dexmedetomidine on basal ganglia neuronal activity (local field potentials) in Parkinson's disease.

Summary

EudraCT number	2016-002680-34
Trial protocol	ES
Global end of trial date	28 November 2018

Results information

Result version number	v1 (current)
This version publication date	24 November 2021
First version publication date	24 November 2021

Trial information

Trial identification

Sponsor protocol code	DEXPAR
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02982512
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Clinica Universidad de Navarra
Sponsor organisation address	AVENIDA PÍO XII, Nº 36, PAMPLONA/IRUÑA, Spain, 31008
Public contact	UCEC, Clinica Universidad de Navarra, 34 948 255 400, ucicec@unav.es
Scientific contact	UCEC, Clinica Universidad de Navarra, 34 948 255 400, ucicec@unav.es

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	31 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 November 2018
Global end of trial reached?	Yes
Global end of trial date	28 November 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study and quantify the possible effect of different doses of dexmedetomidine (0.2-0.6 µg/kg/h) on the local field potentials (deep brain activity) in patients with Parkinson's disease undergoing deep brain stimulation implantation.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 October 2016
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	Spain: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients, of legal age, undergoing DBS placement for Parkinson's disease (NST or GPi) in two stages.

Pre-assignment

Screening details:

14 patients agreed to participate in the trial, but eventually only 12 patients were exposed to the study drug.

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Treatment
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Arm description:

No Intervention: Control recording

Recording of local field potentials without drugs from the deep brain stimulator

Experimental: Dexmedetomidine recording

Recording of local field potentials at different dexmedetomidine concentrations from the deep brain stimulator

Intervention: Drug: Dexmedetomidine

Arm type	Experimental
Investigational medicinal product name	DEXMEDETOMIDINE
Investigational medicinal product code	
Other name	(S)-4-[1-(2,3-Dimethylphenyl)ethyl]-3H-imidazole
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The administration of the drug will be carried out in a single session for 3 hours and 55 minutes. A loading dose of the drug will be administered (0.5 µg / kg in 10 min) and increasing doses of 0.2, 0.3, 0.4, 0.5 and 0.6 µg / kg / h spaced in periods of time of 45 min.

Number of subjects in period 1	Treatment
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	Treatment period
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Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	12	12	
Age categorical			
Units: Subjects			
Adults (18-64 years)	8	8	
From 65-84 years	4	4	
Gender categorical			
Units: Subjects			
Female	6	6	
Male	6	6	

End points

End points reporting groups

Reporting group title	Treatment
Reporting group description:	
No Intervention: Control recording	
Recording of local field potentials without drugs from the deep brain stimulator	
Experimental: Dexmedetomidine recording	
Recording of local field potentials at different dexmedetomidine concentrations from the deep brain stimulator	
Intervention: Drug: Dexmedetomidine	

Primary: Changes in neuronal activity. Dexmedetomidine.

End point title	Changes in neuronal activity. Dexmedetomidine. ^[1]
End point description:	
A loading dose of the drug will be administered (0.5 µg / kg in 10 min) and increasing doses of 0.2, 0.3, 0.4, 0.5 and 0.6 µg / kg / h spaced in periods of time of 45 min.	
End point type	Primary
End point timeframe:	
The administration of the drug will be carried out in a single session for 3 hours and 55 minutes.	

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: With dexmedetomidine infusion, patients became clinically sedated, and at higher doses (0.5-0.6 mg/kg/h) a significant decrease in the characteristic Parkinsonian subthalamic activity was observed ($P < 0.05$ in beta activity). All subjects awoke to external stimulus over a median of 1 (range: 0e9) min, showing full restoration of subthalamic activity. Dexmedetomidine dose administered and plasma levels showed a positive correlation (repeated measures correlation coefficient $\frac{1}{4}0.504$; $P < 0.001$).

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mV/m2				
number (not applicable)	12			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events are collected from the time the patient is treated until the end of their follow-up.

Assessment type	Systematic
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Dictionary used

Dictionary name	ND
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Dictionary version	ND
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Frequency threshold for reporting non-serious adverse events: 5 %

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 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