Clinical trial results:
Dexmedetomidine in awake implantation of neuromodulative systems.

Summary

EudraCT number	2014-001587-35
Trial protocol	NL
Global end of trial date	16 February 2015

Results information

Result version number	v1 (current)
This version publication date	26 January 2020
First version publication date	26 January 2020
Summary attachment (see zip file)	Dexmedetomidine in awake implantation of neuromodulative system (DexMed artikel.pdf)

Trial information

Trial identification

Sponsor protocol code	Feline01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Erasmus MC
Sponsor organisation address	Doctor Molewaterplein 40, Rotterdam, Netherlands,
Public contact	Prof. Dr. F.J.P.M. Huygen, Erasmus Medical Centre, Department of Anesthesiology, f.huygen@erasmusmc.nl
Scientific contact	Prof. Dr. F.J.P.M. Huygen, Erasmus Medical Center, Department of Anesthesiology, f.huygen@erasmusmc.nl

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	20 June 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Patient overall satisfaction.

Protection of trial subjects:

Yes

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2014
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	Netherlands: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment period from 01/09/2014 till 10/02/2015

Pre-assignment

Screening details:

Inclusion criteria: patients aged 18-65 years with an indication for a neurostimulation system

Period 1

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

Blinding implementation details:

Not applicable

Arms

Arm title	Arm 1

Arm description:

Dexmedetomidine infusion

Arm type	Experimental
Investigational medicinal product name	Dexmedetomidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion for infusion in administration system
Routes of administration	Intravenous use

Dosage and administration details:

1 mcg/kg over 10 minutes, followed by 0.6 mcg/kg/hour

Number of subjects in period 1	Arm 1
Started	10
Completed	10

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm 1
Reporting group description: Dexmedetomidine infusion	

Primary: Patient satisfaction

End point title	Patient satisfaction[1]
End point description:	
End point type	Primary
End point timeframe: Within the admission of the patient to the hospital post-operative	

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
Descriptive statistics were used to determine the frequencies of the demographic variables and the outcome parameters, and to describe measures of central tendency and of variability, depending on the shape of the distribution. All analyses were performed using IBM SPSS Statistics version 21 (Armonk, NY, USA).

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: 7				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain relief

End point title	Pain relief
End point description:	
End point type	Secondary
End point timeframe: Perioperative	

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: 10	10			

Statistical analyses

No statistical analyses for this end point

Secondary: patients comfort

End point title	patients comfort

End point description:

End point type	Secondary

End point timeframe:

Postoperative

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: 4				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Secondary: operators comfort

End point title	operators comfort

End point description:

End point type	Secondary

End point timeframe:

Postoperative

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: 4				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Secondary: number of adjustements made in dexmedetomidine infusion

End point title	number of adjustements made in dexmedetomidine infusion

End point description:

End point type	Secondary

End point timeframe:

Perioperative

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Adjustments	10			

Statistical analyses

No statistical analyses for this end point

Secondary: Ramsey score

End point title	Ramsey score

End point description:

End point type	Secondary

End point timeframe:

Prioperative

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: 6				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Secondary: intraoperative standard hemodynamic and respiratory monitoring

End point title	intraoperative standard hemodynamic and respiratory monitoring

End point description:

End point type	Secondary

End point timeframe:

perioperative

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: MAP, HR, SpO2, EtCO2				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Perioperative period	
Assessment type	Systematic
Dictionary used	
Dictionary name	not applicable
Dictionary version	0
Reporting groups	
Reporting group title	All patients

Reporting group description: -

Serious adverse events	All patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)		
Cardiac disorders			
Hypotension/bradycardia			
subjects affected / exposed	10 / 10 (100.00%)		
occurrences (all)	10		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26914618