Clinical trial results:
Dexmedetomidine versus propofol in awake implantation of a neuromodulative system.

Summary

EudraCT number	2015-000964-33
Trial protocol	NL
Global end of trial date	20 April 2018

Results information

Result version number	v1 (current)
This version publication date	28 January 2020
First version publication date	28 January 2020
Summary attachment (see zip file)	DexMedPro RCT (Bruggen_et_al-2019-Acta_Anaesthesiologica_Scandinavica.pdf)

Trial information

Trial identification

Sponsor protocol code	Feline02

Additional study identifiers

ISRCTN number	ISRCTN46302353
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Erasmus Medical Center
Sponsor organisation address	Doctor Molewaterplein 40, Rotterdam, Netherlands, 3015 GD Rotterdam
Public contact	Prof. Dr. F.J.P.M. Huygen, Erasmus Medical Center, 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	01 January 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 April 2018
Global end of trial reached?	Yes
Global end of trial date	20 April 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Patient satisfaction

Protection of trial subjects:

Hemodynamic and respiratory measurements
Pain measurements

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 October 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	Netherlands: 72
Worldwide total number of subjects	72
EEA total number of subjects	72

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)	72
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See inclusion criteria

Pre-assignment

Screening details:

See inclusion criteria:
- Age 18-65 years
- Indication for a neurostimulator
- No exclusion criteria applicable

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind[1]
Roles blinded	Subject, Investigator

Blinding implementation details:

Sedation was performed by an anesthesiologist who could not be blinded to the study group allocation because the sedation protocols for dexmedetomidine and propofol are different. The patient and the operator however were blinded to the study group allocation. In addition, a blinded observer, not involved in the sedation or the interventional procedure, enrolled the patients and performed all perioperative study measurements.

Arms

Are arms mutually exclusive?	Yes
Arm title	Dexmedetomidine group

Arm description:

Dexmedetomidine infusion

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

Dosage and administration details:

Patients in the dexmedetomidine group received a loading dose of dexmedetomidine of 1 µg/kg over 10 minutes to achieve the required level of sedation, followed by a maintenance dose of 0.6 µg/kg/h.

Arm title	Propofol

Arm description:

Propofol infusion

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

Dosage and administration details:

Subjects in the propofol group received a loading infusion of 0.5 mg/kg propofol 1% over 10 minutes followed by a maintenance dose of 2.0 mg/kg/h.

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: The trial was considered single blinded because the anesthesiologist who administered the sedative agents was not blinded. Furthermore the patient, investigator, collector and operator were blinded. This is further reported in the publication.

Number of subjects in period 1	Dexmedetomidine group	Propofol
Started	36	36
Completed	36	36

Baseline characteristics

Reporting groups	
Reporting group title	Dexmedetomidine group
Reporting group description: Dexmedetomidine infusion	
Reporting group title	Propofol
Reporting group description: Propofol infusion	

Reporting group values	Dexmedetomidine group	Propofol	Total
Number of subjects	36	36	72
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)	36	36	72
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	24	27	51
Male	12	9	21

Subject analysis sets	
Subject analysis set title	Dexmedetomidine
Subject analysis set type	Full analysis
Subject analysis set description: Dexmedetomidine infusion	
Subject analysis set title	Propofol
Subject analysis set type	Full analysis
Subject analysis set description: Propofol infusion	

Reporting group values	Dexmedetomidine	Propofol	
Number of subjects	35	34	
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)	35	34	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	23	25	
Male	12	9	

End points

End points reporting groups

Reporting group title	Dexmedetomidine group
Reporting group description: Dexmedetomidine infusion	
Reporting group title	Propofol
Reporting group description: Propofol infusion	
Subject analysis set title	Dexmedetomidine
Subject analysis set type	Full analysis
Subject analysis set description: Dexmedetomidine infusion	
Subject analysis set title	Propofol
Subject analysis set type	Full analysis
Subject analysis set description: Propofol infusion	

Primary: Patient satisfaction

End point title	Patient satisfaction[1]
End point description:	
End point type	Primary
End point timeframe: Postoperative	

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: See trial publication for complete statistical analysis

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
During study period	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	not applicable
Dictionary version	1

Reporting groups	
Reporting group title	Dexmedetomidine group
Reporting group description:	
One patient in the dexmedetomidine group was affected by a SAE	
Reporting group title	Propofol group
Reporting group description: -	

Serious adverse events	Dexmedetomidine group	Propofol group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 35 (2.86%)	0 / 34 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
vasovagal collaps			
subjects affected / exposed	1 / 35 (2.86%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0.5 %

Non-serious adverse events	Dexmedetomidine group	Propofol group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 35 (17.14%)	9 / 34 (26.47%)	
Cardiac disorders			
Hypotension			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 35 (5.71%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Bradycardia			

alternative assessment type: Systematic			
subjects affected / exposed	2 / 35 (5.71%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 35 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Desaturation			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 35 (5.71%)	4 / 34 (11.76%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Unwanted movement			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 35 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	

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/31321763