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A comparison of sedative agents (propofol versus dexmedetomidine) in awake implantation of neuromodulative systems

Submission date
21/09/2015

Recruitment status
No longer recruiting

Registration date
03/12/2015

Overall study status
Completed

Last Edited
24/08/2022

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic (long-term) pain is any pain that has lasted for more than 12 weeks. It is estimated that as many as 20% of adults in Europe experience moderate to severe chronic pain in their lifetime. Often special exercises (physiotherapy) and medications can help ease chronic pain; however some people require more drastic measures. In some cases of severe chronic pain, implanting (placing inside of the body) a neuromodulation device may be recommended. Neuromodulation is a treatment where electrical signals are used to directly stimulate the nervous system (usually the spinal cord), by blocking pain signals. Although once the device is in place it can be very effective at relieving pain, the procedure itself is very painful and so patients are usually sedated. Propofol is a commonly used sedative, as it starts working and wears off very quickly. Propofol, however, can have harmful side effects, such as affecting the heart rate, blood pressure or respiratory system (breathing). It has been suggested that dexmedetomidine could be used as an alternative to propofol, as it is safer for the heart and respiratory system. This medication is often used in operations where the patient is awake, and so using it in neuromodulation implantation could help the patient feel more comfortable in the procedure. The aim of this study is to find out whether patients feel more comfortable and satisfied when dexmedetomidine is used compared to propofol.

Who can participate?
Adults who are suitable for a neuromodulation device implant.

What does the study involve?
Patients are randomly allocated into one of two groups. In the first group, patients are sedated using dexmedetomidine before the procedure. For the second group, patients are sedated using propofol before the procedure. Participants in both groups are given the pain relieving drug remifentanil throughout the procedure, and any negative effects of the medication are noted. Participants complete a questionnaire 24 hours after surgery to find out how well they thought the sedative used worked.

What are the possible benefits and risks of participating?
A potential benefit for participants in the dexmedetomidine group is that it may prove to be safer than propofol and so the risk of complications is lower. Risks of participating include the standard risks associated with surgery and sedation.

Where is the study run from?
Erasmus Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
February 2015 to December 2017

Who is funding the study?
Erasmus Medical Center (Netherlands)

Who is the main contact?
1. Miss Feline ter Bruggen (Public)
2. Professor Frank Huygen (Scientific)

Contact information

Type(s)
Public

Contact name
Miss Feline ter Bruggen

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

2015-000964-33

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL52755.078.15

Study information

Scientific Title
Dexmedetomidine versus propofol in awake implantation of neuromodulative systems

Acronym
DexMedPro

Study objectives
The objective of this study is to assess the overall patient satisfaction with the awake implantation of a neuromodulative system comparing dexmedetomidine with propofol (standard) as a sedative.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee Erasmus Medical Center, 17/09/2015, ref: NL5275507815

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Chronic pain

Interventions

A randomisation list is provided by a statisticus. There are two treatment arms, one is the propofol arm and the other is the dexmedetomidine arm. The total duration of treatment is approximately 3 hours for the implantation of a neuromodulative system. The follow-up involves a patient satisfaction questionnaire, patient comfort score, measurement of hemodynamic data and respiration at 24 hours after surgery before the patient is going home.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. Dexmedetomidine 2. Propofol

Primary outcome measure
Patient satisfaction during surgery, measured by using the Patient Sedation Satisfaction Index (PSSI) at 24 hours after surgery.

Secondary outcome measures
1. Hemodynamics (Mean arterial pressure, systolic blood pressure, diastolic blood pressure, heart rate) are measured before surgery, every 5 minutes during surgery and 24 hours after surgery
2. Respiration (SpO2) is measured by a peripheral saturation measurement before surgery, every 5 minutes during surgery and 24 hours after surgery
3. Sedation is measured using the Ramsey sedation score (RSS) before surgery, every 5 minutes during surgery and 24 hours after surgery
4. Pain is measured using the numeric rating score (NRS) before surgery, every 5 minutes during surgery and 24 hours after surgery
5. Complications are noted during and after surgery from medical observations
6. Cost-effectivity analysis measures the costs of medicine and patient satisfaction during surgery and 24 hours after surgery
7. Patients comfort and operators comfort is measured by using a comfort score 24 hours after surgery
8. The number of adjustments of dexmedetomidine or propofol titration is noted during surgery by using a count system

Overall study start date
01/02/2015

Completion date
20/04/2018

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years.
2. Indication for implantation of a neuromodulative system

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

Total final enrolment
72

Key exclusion criteria
1. Hypersensitivity of active part of one of any of the excipients
2. AV-blok (II or III)
3. Acute cerebrovascular disease
4. Pregnancy
5. Acute epilepsy
6. Severe liver dysfunction
7. Use of a beta blocker
8. Use of medications causing hypotension or bradycardia.
9. Psychologically unstable
10. Communication problem
11. Heart rate <60bpm
12. Allergy for soya or peanuts
13. Heart failure
14. Severe heart disease
15. Electroconvulsive therapy (ECT)
16. ASA III, IV, V

Date of first enrolment
05/10/2015

Date of final enrolment
05/10/2017

Locations

Countries of recruitment
Netherlands

Study participating centre

Erasmus University Medical Center
's-Gravendijkwal 230
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Sponsor information

Organisation
Erasmus Medical Center

Sponsor details
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Rotterdam
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3015 CE

Sponsor type
Hospital/treatment centre

Website
www.erasmusmc.nl

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medisch Centrum

Alternative Name(s)
Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Publication of results in a peer reviewed journal.

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr FFJA ter Bruggen (f.terbruggen@erasmusmc.nl) (SPSS dataset).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2019	16/01/2020	Yes	No
Protocol file	version 3	14/08/2015	15/08/2022	No	No