Dexmedetomidine in awake implantation of neuromodulative systems.

Published: 09-07-2014
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The purpose of this study is to observe the usability of Dexmedetomidine and to determine the overall satisfaction of the patient.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON41067

Source
ToetsingOnline

Brief title
DexMed

Condition

- Spinal cord and nerve root disorders

Synonym
Awake implantation of a neuromodulative system.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Awake Implantation, Dexmedetomidine, Neuromodulative system, Sedation

Outcome measures

Primary outcome

The primary study parameter is overall patient satisfaction measured by a questionnaire.

Secondary outcome

The secundary study parameters:

- Sedation scale (Ramsey score),

- Clinical pain relief (NRS score),

- Patient comfort score and operator comfort score

- Hemodynamic measuring (blood pressure and heart rate)

- Respiratory frequency measuring (capnography) and pulsoximetry.

- Measurement of the number of adjustments of Dexmedetomidine titration during procedure

Study description

Background summary

Dexmedetomidine has proven to be a good sedative in several diagnostic and therapeutic *awake* procedures. We want to observe the usefulness of Dexmedetomidine in the awake implantation of a neuromodulative system. This is a painful procedure, which can be uncomfortable due to the long-term prone position. Deep sedation is undesirable because the patients have to be cooperative during the procedure.
Compared to commonly used sedatives and analgesics, such as remifentanil and propofol, Dexmedetomidine appears to be hemodynamically and respiratory safer, more comfortable for the patient while at the same time it is possible for the patient to be fully cooperative.

Study objective

The purpose of this study is to observe the usability of Dexmedetomidine and to determine the overall satisfaction of the patient.

Study design

This is a prospective observational study with an intervention.

Intervention

Loading infusion of the sedative Dexmedetomidine.

Study burden and risks

The potential benefits of the use of Dexmedetomidine during procedure include no blur of consciousness; no decline of cognitive skills; the patient is required less alert, is sleeping but still arousable, cooperative and instruct able without any agitation. Dexmedetomidine has a good anxiolytic effect, a light analgesic effect and causes no respiratory depression. It makes a lower dose of propofol and remifentanil possible. Side effects are the possibility of hypotension and bradycardia. A disadvantage is that is has no amnesic effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients need to be between 18 and 65 years.;- Patients have an indication for implantation of a neuromodulative system.

Exclusion criteria

- Hypersensitivity of active part of one of any of the excipients
- AV-block (II or III)
- Acute cerebrovascular disease
- Pregnancy
- Acute epilepsy
- Severe liver dysfunction
- Use of a beta blocker.
- Psychologically unstable
- Communication problem.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014

Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexdor
Generic name:	Dexmedetomidine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	09-07-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-07-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2014-001587-35-NL
CCMO	NL49012.078.14