# Dexmedetomidine versus propofol in the awake implantation of a neuromodulative system.

Published: 13-07-2015
Last updated: 16-04-2024

The purpose of this study is to observe the usability of dexmedetomidine compared to the standard therapy (propofol) and to determine the overall satisfaction of the patient.

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

## Summary

### ID

NL-OMON44659

**Source**
ToetsingOnline

**Brief title**
DexMedPro

### 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, Propofol, 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 number of adjustments of dexmedetomidine titration during

procedure

- Measurement of number of (extra) bolus of remifentanil during procedure

- Cost-efficacy analysis

- Complications

# 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 compared to the standard therapy (propofol) and to determine the overall satisfaction of the patient.

### Study design

This is a double-blind randomized controlled trial with an intervention.

### Intervention

Administration of dexmedetomidine or propofol.

### 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 instructable 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

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3000CA
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3000CA
NL

# 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-blok (II or III)
- Acute cerebrovascular disease
- Pregnancy
- Acute epilepsy
- Severe liver dysfunction
- Use of a beta blocker
- Use of medications causing hypotension or bradycardia.
- Psychologically unstable
- Communication problem
- Heart rate <60bpm
- Allergy for soya or peanuts
- Heart failure
- Severe heart disease
- Electroconvulsive therapy (ECT)
- ASA III, IV, V

# Study design

## Design

| | |
|---|---|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 22-10-2015 |
| Enrollment: | 72 |
| Type: | Actual |

## Medical products/devices used

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

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 13-07-2015 |
| Application type: | First submission |

| | |
|---|---|
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 17-09-2015 |
| 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 | EUCTR2015-000964-33-NL |
| CCMO | NL52755.078.15 |