Does size matter? Clinical outcome related to the extent of posterior (cranio)cervical fixations. A prospective international multicenter study.

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A study on extent-related outcome and complications for degenerative cervical spinal disease has not yet been performed. Results of this study may form the basis for a guideline regarding the extent of fixation in degenerative cervical spinal…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational non invasive

Summary

ID

NL-OMON41054

Source
ToetsingOnline

Brief title
CONNECT

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
degenerative disease of the vertebrae, neck pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Medtronic,Medtronic B.V.

Intervention

Keyword: cervical, fixation, posterior

Outcome measures

Primary outcome

The primairy study parameter will be the Neck Disability Index.

Secondary outcome

Secondary clinical outcome parameters are:

- Patient perceived outcome: Likert scale

- Pain: VAS for neck pain an VAS for arm pain

- Quality of life: SF-36 and EQ-5D

- Mental Health: HADS

- Neurological status: JOA scale

Study description

Background summary

Degenerative disease is the most common indication for cervical fixation, as it is the most common cause of myelopathy and radiculopathy, causing progressive functional disability and impairment.
In general, there is an indication for surgery when there is neurological deficit or pain and lack of response to conservative treatment, spinal cord compression with significant neurologic deterioration, mechanical instability, or substantial cervical vertebral deformity. There are several indications for posterior cervical instrumented spondylodesis, i.e. fixation. In most cases, the spondylodesis is done secondary to decompression of the dural sac and/or a spinal root(s). In other instances, spondylodesis is performed to prevent compression of neural structures. The surgical technique and the extent of the

fixation are currently based on patient related factors, such as age, comorbidity and antomy, and the preference of the traeting surgeon based on his expertise and experience with the procedure.

Study objective

A study on extent-related outcome and complications for degenerative cervical spinal disease has not yet been performed. Results of this study may form the basis for a guideline regarding the extent of fixation in degenerative cervical spinal disease. Furthermore, analysis of the influence of patient related factors on the clinical outcome and rate of complications will be informative for the treating surgeon.

Study design

This study is a prospective, international, muticenter study to assess the clinical outcome of posterior (cranio)cervical fixations, differentiated according to the extent of the surgery. During the inclusion period of one year, all posterior (cranio)cervical fixations of patients who meet the inclusion criteria and heave given written informed consent to participate in this study, will be registered in a secured database. Baseline (preoperative) and perioperative data will be registered. During the follow-up period ot two years, all primary and secondary study parameters will be registered. At the end of the study, which is defined as the last patient's last follow-up, data analyses will be performed.

Intervention

(cranio)cervical fixation

Study burden and risks

Participating in the study will not pose additional risks, because they will be treated by usual care. Patients will be asked to complete questionnaires.

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

Male and female patients aged 18 * 80 years planned for posterior (cranio)cervical fixation
Clinical signs and symptoms, i.e. myelopathy or radiculopathy, due to degenerative cervical spine disease
Radiological diagnosis at spinal level in accordance with clinical signs and symptoms
Patient is able and willing to comply with the follow-up schedule and protocol

Exclusion criteria

Additional anterior surgery required
Cervical spine surgery in the last 6 months
Other cervical spinal disease, e.g. trauma, tumour

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-04-2015
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	plates and screws
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-02-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21529
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50062.058.14
OMON	NL-OMON21529