

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

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Degenerative disease of the cervical spine is the most common indication for (cranio)cervical fixation, as it is the most common cause of myelopathy and radiculopathy, causing progressive functional disability and impairment. However, consensus has...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21529

Bron

Nationaal Trial Register

Verkorte titel

COnnECT.

Aandoening

Degenerative cervical spine disease in male and female patients aged 18 to 80 years

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)

Overige ondersteuning: Medtronic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical outcome: Neck Disability Index (NDI)

Toelichting onderzoek

Achtergrond van het onderzoek

All patients aged between 18 and 80 years with degenerative cervical spine disease requiring posterior (cranio)cervical fixation, with or without decompression, will be asked to participate in this study. Those who meet the inclusion criteria and have given written informed consent will be included in the study. The aim of this study is to prospectively observe and assess the clinical outcome of posterior (cranio)cervical fixations in patients with degenerative cervical spine disease, differentiated for the extent of the procedure.

Doel van het onderzoek

Degenerative disease of the cervical spine is the most common indication for (cranio)cervical fixation, as it is the most common cause of myelopathy and radiculopathy, causing progressive functional disability and impairment. However, consensus has yet to be reached on the extent of the procedure. The extent is, in part, based on the clinical outcome and complications of the procedure. The aim of this study is to prospectively observe and assess the clinical outcome of posterior (cranio)cervical fixations in patients with degenerative cervical spine disease, differentiated for the extent of the procedure

Onderzoeksopzet

Follow-up visits are scheduled to be 3 months, 6 months, 1-2- 5 years.

Onderzoeksproduct en/of interventie

Posterior (cranio)cervical fixations stratified into the following five groups:

1. C0 to C2/3;
2. C0 to C4/5/6;
3. C0 to T2/3;
4. Cervical fixation > 2 levels;

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male and female patients aged between 18 and 80 years;
2. Degenerative cervical spine disease requiring posterior (cranio)cervical fixation, with or without decompression;
3. Radiological findings in accordance with clinical signs and symptoms;
4. Patient is able and willing to comply with the follow-up schedule and protocol;

5. Patient is able to provide informed written consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Additional anterior fixation required;
2. Cervical spine surgery in the last 6 months;
3. Other cervical spine disease, e.g. trauma, tumor

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	30-07-2014

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41054

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4349
NTR-old	NTR4705
CCMO	NL50062.058.14
OMON	NL-OMON41054

Resultaten

Samenvatting resultaten

N/A