Interbody fusion in the treatment of cervicobrachial syndrome; a prospective trial of porous titanium cervical cages.

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Documentation of the patients' functional recovery and quantification of fusion after implantation of 3-D trabecular titanium cages on the short and long term. These data will be compared with the recently performed randomized CASCADE trial on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON43762

Source
ToetsingOnline

Brief title
The EFFECT trial (Examination of Fast Fusion with EIT Cellular Titanium)

Condition

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

Synonym
cervical herniated disc

Research involving
Human

Sponsors and support

Primary sponsor: neurochirurgie
Source(s) of monetary or material Support: EIT Emerging Implant Technolgies GmbH

Intervention

Keyword: cage, cervical, fusion, titanium

Outcome measures

Primary outcome

The primary outcome measure is improvement in the Neck and Disability Index (NDI) one year after surgery.

Secondary outcome

Secondary outcome measure is the temporal evaluation of bony fusion using dynamic lateral flexion-extension radiographs that will be quantitatively analysed. Other outcome measures include improvement in arm pain and neck pain (VAS), EuroQol-5D, patients' perceived recovery, and perioperative variables including operating time, blood loss, length of hospital stay, and adverse events.

Study description

Background summary

Anterior cervical discectomy is the basic surgical treatment for patients with radicular pain caused by cervical disc herniation unresponsive to conservative treatment. At present, anterior cervical discectomy and interbody fusion with a Polyetheretherketone (PEEK) plastic cage is considered as the golden standard, although PEEK is a bio-inert material generating peri-implant fibrosis. In a recent randomized controlled trial (CASCADE trial), PEEK has been compared to ceramic cages. Currently, biocompatible porous 3-D printed titanium has become available in spinal implants. In-vitro and in-vivo studies using porous 3-D printed titanium implants in various animal species, have demonstrated high

osteo-integrative and fusion capacity, although clinical comparative studies have not been conducted yet.

Study objective

Documentation of the patients' functional recovery and quantification of fusion after implantation of 3-D trabecular titanium cages on the short and long term. These data will be compared with the recently performed randomized CASCADE trial on cervical cages. Whether porous titanium cervical cages have more favourable clinical and radiological results as compared to the golden standard, has to be determined by this trial.

Study design

The EFFECT study is designed as a prospective consecutive cohort trial, with a total follow-up period of 1 year.

Intervention

Anterior cervical discectomy with interbody fusion by implantation of 3-D trabecular titanium cage (EIT Cellular Titanium®).

Study burden and risks

Besides the known complications of an anterior cervical approach, there are implant related risks like displacement, subsidence,
or breakage. The outpatient control will be more frequently than usual and patients are asked to fill out several questionnaires.

Contacts

Public
Selecteer

Heubergweg 8
Tuttlingen 78532
NL
Scientific
Selecteer

Heubergweg 8
Tuttlingen 78532
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age 18 75 years.
* Radicular signs and symptoms in one or both arms (i.e., pain, paraesthesiae or paresis in a specific nerve root distribution) or symptoms and signs of myelopathy.
* At least 8 weeks prior conservative treatment (i.e., physical therapy, pain medication).
* Radiographic diagnosis of cervical disc herniation and/or osteophyte at 1 level (C3-C4 to C7-T1) in accordance with clinical signs and symptoms.
* Written informed consent.

Exclusion criteria

* Previous cervical surgery (either anterior or posterior)
* Increased motion on dynamic studies (> 3 mm)
* Neck pain only (without radicular or medullary symptoms)
* Infection
* Osteoporosis
* Neoplasma or trauma of the cervical spine
* Spinal anomaly (Klippel Feil, Bechterew, OPLL)
* Severe mental or psychiatric disorder
* Inadequate Dutch language
* Planned (e)migration abroad in the year after inclusion
. Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	cellular titanium cage
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-06-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	20-01-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	26-01-2017
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL51781.098.14