Interbody fusion devices in the treatment of cervicobrachial syndrome; a blinded randomised trial of cancellous structured ceramic (CSC) versus PEEK cages.

Published: 20-10-2011
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To compare functional recovery of the patient and the fusion status of ceramic cages versus PEEK cages on the short and long term.

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-OMON41376

Source
ToetsingOnline

Brief title
CASCADE Trial

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: Amedica Corporation
Source(s) of monetary or material Support: Amedica Corporation

Intervention

Keyword: cage, cervical, fusion, pain

Outcome measures

Primary outcome

Neck Disability Index (NDI)

Secondary outcome

Neckpain, armpain, patient's perceived recovery, fusion, EuroQol, re-operations

and complications.

Study description

Background summary

Anterior discectomy with intercorporal fusion with PEEK cages is the golden standard in the treatment of patients with cervicobrachialgia due to a herniated disc and/or osteophyte. The hydrophobic characteristics of PEEK however, result in bone growth around the cage with possible risk of subsidence. The newly developed cancellous structured ceramic (CSC) cages have hydrophylic properties which facilitate bone adherence and incorporation into the cage. Moreover, ceramics have desirable imaging properties. A randomised controlled trial on ceramic cages versus PEEK cages has never been performed.

Study objective

To compare functional recovery of the patient and the fusion status of ceramic cages versus PEEK cages on the short and long term.

Study design

Prospective randomised controlled blinded trial with a follow-up of 2 years.

Intervention

Anterior discectomy with ceramic cages versus anterior discectomy with PEEK cages.

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
Amedica Corporation

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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 between 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 acute or chronic 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).
* Severe segmental kyphosis of the involved disc level (> 7 degrees).
* Patient cannot be imaged with MRI.
* Neck pain only (without radicular or medullary symptoms).
* Infection.
* Metabolic and bone diseases (osteoporosis, severe osteopenia).
* 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.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-12-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	20-10-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-01-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-03-2015
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	NL36103.098.11