A randomised multicenter study comparing anterior cervical discectomy with or without interbody fusion and arthroplasty in the treatment of cervical disc herniation.

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To show whether Active C disc prosthesis is more effective than anterior discectomy with or without interbody fusion 1 year after surgery. Moreover, the incidence of adjacent disc degeneration will be evaluated 5 years after surgery.

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-OMON35197

Source
ToetsingOnline

Brief title
The NECK 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
Armpain, cervical disc herniation

Research involving
Human

Sponsors and support

Primary sponsor: Aesculap AG
Source(s) of monetary or material Support: B Braun Medical B.V. Aesculap

Intervention

Keyword: Cage, Cervical, Disc, Prosthesis

Outcome measures

Primary outcome

The functional assessment of the patient self on an illness specific

questionnaire: *Neck Disability Index*.

Secondary outcome

Neck and arm pain (VAS), quality of life (SF-36), emotional status determined

by the Hospital Anxiety Depression Scale (HADS), work experience measured by

the Karasek Job Content Questionnaire, perceived recovery of the patient,

researchnurse and surgeon (Likert and Macnab), complications, incidence of

re-operations, costs (direct and indirect) and incidence of adjacent disc

degeneration (criteria of Hilibrand and Goffin).

Study description

Background summary

Patients with cervical radicular syndrome due to disc herniation refractory to conservative treatment are offered surgical treatment. Anterior cervical discectomy is the standard procedure, often in combination with interbody fusion to maintain disc height. Accelerated adjacent disc degeneration is a known entitity on the long term. Recently, cervical disc prosthesis are developed to maintain motion and possibly reduce the incidence of adjacent disc

degeneration. Up till now, no randomised comparative trial has been performed between anterior discectomy with or without intercorporal fusion and disc prosthesis.

Study objective

To show whether Active C disc prosthesis is more effective than anterior discectomy with or without interbody fusion 1 year after surgery. Moreover, the incidence of adjacent disc degeneration will be evaluated 5 years after surgery.

Study design

The study is a multicenter randomised trial with a follow-up period of 5 years.

Intervention

Patients will be randomised in 3 groups: anterior discectomy without interbody fusion, anterior discectomy with interbody fusion, and anterior discectomy with Active C disc prosthesis.

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

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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 18-65 years
·Radicular signs and symptoms in one or both arms
·At least 8 weeks prior conservative treatment
·Radiographic diagnosis of cervical disc herniation and/or osteophyte at 1 level
.No previous cervical surgery
·Informed consent

Exclusion criteria

.Increased motion on dynamic studies (> 3 mm)
·Involved disc level fused or very narrow
·Severe kyphosis of the involved disc level
·Neck pain only
·Infection
·Metabolic and bone diseases
·Neoplasma or trauma
·Spinal anomaly (Klippel Feil, Bechterew, OPLL)
·Severe mental or psychiatric disorder
·Inadequate Dutch language

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-10-2010
Enrollment:	750
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2012
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

No registrations found.

In other registers

Register	ID
CCMO	NL21327.058.08