Cervical spine movement, before and after anterior cervical discectomy (ACD). ACD, pure intervertebral discectomy (1) compared to intervertebral discectomy followed by implantation of an intervertebral disc prosthesis (2) in patients with a radicular syndrome. A randomised study

Published: 02-05-2007
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Objective of the study is to verify whether the movement pattern after anterior cervical discectomy normalises, in case of implantation of a cervical disc prosthesis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON38336

Source
ToetsingOnline

Brief title
Cervical spine movement, before and after anterior cervical discectomy.

Condition

- Bone disorders (excl congenital and fractures)
- Spinal cord and nerve root disorders
- Head and neck therapeutic procedures

Synonym
cervical disc prolaps, cervical radiculopathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Braun Medical B.V.,Industrie

Intervention

Keyword: Anterior cervical discectomy, Cervical radicular syndrome, disc arthroplasty

Outcome measures

Primary outcome

Movement testing of the cervical vertebral column in both groups according the

given methods. Comparing both investigational arms, defined to normal values.

Secondary outcome

Clinical condition of the different patients groups according the used

outcome/scoring scales

Study description

Background summary

Standard treatment for cervical radicular syndrome based on a cervical disc protrusion is anterior cervical discectomy with or without intended fusion. In case fusion is not intended, in 70% of the cases the operated level will fuse spontaneously. The movement of the cervical vertebral column will change after anterior cervical discectomy. The pressure in the intervertebral disc above or below the operated level will increase, which leads to an increased degeneration of these intervertebral disc levels. Artificial disc implants are developed to prevent this increased degeneration by restoring the anatomy and functionality of the operated level. Studies showed that a disc implant allows flexion and deflexion but whether this is a natural movement pattern is unclear. The underlying protocol intends to investigate the movement pattern

after implantation of a cervical disc implant. A natural movement pattern is an obligatory condition to prevent increased degeneration in the adjacent levels.

Study objective

Objective of the study is to verify whether the movement pattern after anterior cervical discectomy normalises, in case of implantation of a cervical disc prosthesis.

Study design

Open randomised trial. The control group consists of patients who receive a standard treatment, simple anterior cervical discectomy. The study group consists of patients who receive the standard treatment with additional implantation of a cervical disc prosthesis.
The reference values will be established on the basis of a historical control group and an also analyzed group of healthy subjects.

Intervention

Anterior cervical discectomy (standard treatment option) in the control group, additional impantation after discectomy of a disc prosthesis in the investigational group.

Study burden and risks

The study requires three times fluoroscopy of the cervical vertebral column to investigate movement (0.1 mSv /study), which takes several minutes. Besides the patient is asked to fill out scoring forms which will take 15 to 20 minutes a time. There will also be a short fysical examination, which takes about 5 minutes. These activities are planned in succession to each other so the total time spent on filling out the questionairres and the examinations is about 30 minutes.
The literature reports no additional operation related risks of implantation of an cervical disc prosthesis. Main reported implant failure is fusion, which will happen in simple anterior cervical discectomy in 70% of the cases.

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

Studygroups:
Clinical moniradicular syndrome C6 or C7
age between 18 and 55
Monosegmental abnormality on MRI
Able to perform flexion and extension movement by the patient self
Segmental Range of Motion (ROM) > 2 degrees
Willingness to Follow up
Informed consent;Control-group:
Age 18-55
Subject is able to actively perform flexion and extension movement
Informed consent
Anamnestic and based on the neck disability index no neck complaints (NDI <5)

Exclusion criteria

-Cervical spinal surgery in history
-Degenerative spinal deformities on multiple levels
-Positive sign of L'Hermitte
-Active infection

-Immature bone
-Cervical spine tumor
-Radiotherapy in history
-Pregnancy
-Cervical myelopathy
-Not able to speak and understand the Dutch language;Control-group:
-Cervical spinal surgery in history
-X-ray imaging of head/cervical spine/thorax in the previous year
-Degenerative spinal deformities (vertebral bodies or zygapophysial joints)
-Positive sign of L'Hermitte
-Active infection
-Immature bone
-Cervical spine tumor
-Radiotherapy in history
-Pregnancy
-Cervical myelopathy
-Not able to speak and understand the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2007
Enrollment:	47
Type:	Actual

Medical products/devices used

Generic name:	cervical disc prosthesis

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-05-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-10-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-09-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT00868335
CCMO	NL14240.068.06