Economic evaluation of the surgical treatment of cervical myelopathy, radiculopathy, or myeloradiculopathy: anterior cervical discectomy with arthroplasty versus anterior cervical discectomy with fusion.

Published: 28-04-2020
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The aim of the proposed study is to examine whether ACDA compared to ACDF is preferable in terms of costs, effectiveness and utility from a hospital and a societal perspective.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON55188

Source
ToetsingOnline

Brief title
Cervical Arthroplasty Cost Effectiveness Study (CACES)

Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
Cervical myelopathy and/or radiculopathy, nerve and/or spinal cord compression in the neck

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: IO1599 Onderzoeksfonds Neuro-Ortho Zuyderland

Intervention

Keyword: Anterior cervical discectomy with arthroplasty, Anterior cervical discectomy with fusion, Cost-effectiveness, Economic evaluation

Outcome measures

Primary outcome

This study consists of three parts: clinical effectiveness, economic evaluation and process evaluation. For clinical effectiveness we investigate whether the rate of symptomatic ASD and re-operation is lower after ACDA in comparison with ACDF. Moreover, we evaluate whether ACDA is non-inferior to ACDF in terms the Neck Disability Index, the Visual Analogue Scale score for neck and arm pain, the Hospital Anxiety Depression Scale, Generic Quality of Life, and the Modified Japanese Orthopedic Association score for myelopathy patients. For the economic evaluation, we analyse the cost-effectiveness and the cost-utility of ACDA in comparison with ACDF from a societal perspective. For the process evaluation interviews will be held with patients, informal care givers and professionals. We compare outcomes between groups at baseline and every 6 months till 4 years postoperatively.

Secondary outcome

Not applicable.

Study description

Background summary

The standard surgical procedure for treating patients with single or multilevel cervical degenerative disc disease (CDDD) and symptoms of radiculopathy and/or myelopathy is anterior cervical discectomy, either with fusion (ACDF) or without. Adjacent segment disease (ASD) occurs in approximately 25% of patients during 10 years follow-up. More than 2/3 of these patients need additional surgery. Anterior cervical discectomy with arthroplasty (ACDA) was developed in an effort to reduce the incidence of ASD by preserving physiological motion in the operated segment.

Study objective

The aim of the proposed study is to examine whether ACDA compared to ACDF is preferable in terms of costs, effectiveness and utility from a hospital and a societal perspective.

Study design

The study design will be a prospective randomised controlled trial.

Intervention

The intervention group receives ACDA (n=89) and the control group receives ACDF (n=89).

Study burden and risks

The burden for patients in this study is low. The surgical procedures of the intervention and control group are comparable and the complication risks are similar. Patients are only asked to fill in questionnaires during 4 years postoperatively. This study can lead to important new insights and might change the standard surgical for patients with CDD in the Netherlands.

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

- Patients >= 18 and <= 75 years of age.
- Single or 2-level CDDD, between C3 and C7.
- Symptoms of myelopathy, radiculopathy, or myeloradiculopathy.
- In case of pure radiculopathy: refractory to at least 6 weeks of conservative therapy.
- In case of myelopathy: symptomatic myelopathy.

Exclusion criteria

- Kellgren-Lawrence score of 4 at the target level(s).
- Indication for (additional) posterior surgical approach.
- Indication for surgery on three or more levels.
- Previous ventral surgery of the cervical spine.
- Traumatic origin of the compression.
- Previous radiotherapy to the cervical spine.
- Metabolic bone disease.
- Inflammatory spinal disease: e.g. Ankylosing spondylitis, Forestier*s disease.
- Infection of the cervical spine.

- Unable to fill out Dutch questionnaires.
- Informed consent not possible.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	23-11-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	07-10-2021
Application type:	Amendment

Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	27-03-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	22-01-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	12-11-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NCT04623593
CCMO	NL72534.096.20