The Netherlands cervical kinetics trial, Neck

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27181

Source
NTR

Brief title
the NE(therlands) C(ervical) K(inetics) trial

Health condition

Cervical; Disc; Cage; Prothesis.

Cervicaal; Discus; Cage; Prothese.

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: B. Braun Medical B.V. Aesculap

Intervention

Outcome measures

Primary outcome

The incidence of Accelerated Adjacent Disc Degeneration (AADD) after cervical disc arthroplasty and discectomy with or without fusion.

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)

- complications

- incidence of re-operations

- costs (direct and indirect)

- 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 prothesis.

Study objective

The incidence of symptomatic adjacent disc generation after cervical disc arthroplasty is equal to anterior discectomy with or without interbody fusion at 2 years after surgery.

Study design

Follow up of all patients will be performed at 8, 52, 104, 156, 208 and 260 weeks after surgery.

Questionnaires will be send by mail.

Intervention

Patients who fit the in- and exclusiecriteria for the trial will be randomised into three groups.

Group A: anterior cervical discectomy (ACD or sec)

Group B: anterior cervical discectomy with interbody fusion (ACDF or fusion)

Group C: anterior cervical discectomy with disc prothesis (ACPD or motion)

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-65 years

2. Radicular signs and symptoms in one or both arms

3. At least 8 weeks prior conservative treatment

4. Radiographic diagnosis of cervical disc herniation and/or osteophyte at 1 level

5. No previous cervical surgery

6. Informed consent

Exclusion criteria

1. Increased motion on dynamic studies (> 3 mm)

2. Involved disc level fused or very narrow

3. Severe kyphosis of the involved disc level

4. Neck pain only

5. Infection

6. Metabolic and bone disease

7. Neoplasma or trauma

8. Spinal anomaly (Klippel Feil, Bechterev, OPLL)

9. Severe mental or psychiatric disorder

10. Inadequate Dutch language

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	128
Type:	Actual

Ethics review

Positive opinion

Date:	22-04-2008
Application type:	First submission

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
NTR-new	NL1243
NTR-old	NTR1289
Other	: P08.011
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A