A prospective, randomised multicentre study comparing cervical anterior discectomy without fusion, with fusion or with arthroplasty

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/02/2006		[X] Protocol		
Registration date 11/04/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category Musculoskeletal Diseases	Individual participant data		
() /() /() /	MUSCUIOSKEIEFALDISEASES			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Roland Donk

Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A prospective, randomised multicentre study comparing cervical anterior discectomy without fusion, with fusion or with arthroplasty

Acronym

PROCON

Study objectives

PROCON was designed to assess the clinical outcome, development of adjacent disc disease and costs of cervical anterior discectomy without fusion, with fusion using a stand-alone cage and implantation of a Bryans disc prosthesis. The Bryan's disc is supposed to act better than the other two.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Ethics Committee have fully approved the study and its design on the 25th June 2003 (ref: 103/2003).

Study design

A multicentre, randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cervical disk herniation with radiculopathy

Interventions

Anterior surgery without any fusion, with fusion using a cage or arthoplasty

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Clinical outcome after one year estimated by patient self reports:

- 1. McGill pain questionnaire-Dutch language version (MPQ-DLV)
- 2. Neck disability
- 3. 36-item short form questionnaire (SF-36)

Key secondary outcome(s))

- 1. Kyphosis on plain x-rays after one and five years
- 2. MRI at five years to elucidate the quality of the adjacent discs

Completion date

01/09/2009

Eligibility

Key inclusion criteria

- 1. Aged 18 to 55 years
- 2. Cervical monoradicular symptoms
- 3. Magnetic resonance imaging (MRI): herniated cervical intervertebral disc and/or osteophyte in accordance with clinical symptoms and signs
- 4. Involved level not fused

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Symptoms and/or signs of myelopathy
- 2. Previous cervical surgery
- 3. Psychiatric or mental disease
- 4. Involvement of liability procedure
- 5. Alcoholism (drinking more than five units)
- 6. Insufficient knowledge of the Dutch language
- 7. Participation in another study
- 8. Two or more levels involved

Date of first enrolment

01/09/2004

Date of final enrolment

01/09/2009

Locations

Countries of recruitment

Netherlands

Study participating centre Weg door Jonkerbos 100

Nijmegen

Sponsor information

Organisation

Canisius-Wilhelmina Hopsital (CWZ) (The Netherlands)

ROR

https://ror.org/027vts844

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Canisius-Wilhelmina Hopsital (CWZ) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/08/2017	01/03/2021	Yes	No
Results article	results	01/11/2020	01/03/2021	Yes	No
Results article	results	01/02/2018	01/03/2021	Yes	No
Results article	results	01/05/2017	01/03/2021	Yes	No
Protocol article	protocol	10/11/2006		Yes	No