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

Submission date
19/02/2006

Recruitment status
No longer recruiting

Registration date
11/04/2006

Overall study status
Completed

Last Edited
01/03/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

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

Overall study start date
01/09/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
270

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
Netherlands
6532 SZ

Sponsor information

Organisation
Canisius-Wilhelmina Hopsital (CWZ) (The Netherlands)

Sponsor details
Weg door Jonkerbos 100
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027vts844

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Canisius-Wilhelmina Hopsital (CWZ) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	10/11/2006		Yes	No
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