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Laminectomy without or with dorsal Fusion for cervical myeloradiculopathy: a randomised trial

Submission date	Recruitment status	[_] Prospectively registered
13/02/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/06/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2012	Musculoskeletal Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.nccn.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2007/01

Study information

Scientific Title

Acronym
LamiFuse

Study objectives
Patients that are surgically treated for signs and symptoms due to a stenosis of the cervical spinal canal have a better clinical outcome when a dorsal fusion is performed in addition to a laminectomy compared to those that have solely a laminectomy.

At the end of the study, the quality of life, complications, and the costs will be evaluated comparing these two treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics board (Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen) on the 8th May 2007 (ref: CMO nr. 2007/052 and ABR nr: NL166633.091.07).

Study design
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 myelopathy due to cervical spinal stenosis

Interventions
Laminectomy versus laminectomy and fusion.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Clinical outcome measured by the modified version of the Japanese Orthopedics Association scale (mJOA) score. This will be measured at six weeks, three months and one year after surgery.

Secondary outcome measures
1. Quality of life, measured using the 36-item Short Form health survey (SF-36)
2. Complications
3. Costs

These will be measured at six weeks, three months and one year after surgery.

Overall study start date
09/01/2007

Completion date
09/01/2010

Eligibility

Key inclusion criteria
1. Patients with a minimal age of 60 years
2. At neurologic examination myelopathic changes must be apparent
3. At Magnetic Resonance Imaging (MRI), concordant stenotic alterations at the cervical level(s) must be present
4. At the plain sitting lateral radiograph a lordotic spine must be shown
5. The shape of the cervical spine is lordotic when the vertebral bodies of C3 to C6 are in front of a line drawn from a point of the posterior inferior part of C2 to a point at the posterior superior part of C7

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
1. Previous cervical surgery for myelopathic signs and symptoms
2. Solely radiculopathy, or most important complaint
3. Unable to undergo MRI
4. Life expectancy less than two years
5. Other diseases interfering with neurologic symptoms and signs, for example spinal cord

glioma, thoracic herniated disc with spinal cord compression, multiple sclerosis etc.
6. Rheumatoid arthritis
7. Trauma to the neck in history
8. Diseases interfering with rehabilitation, for example severe cardiac congestive disease
9. Participation in another study

Date of first enrolment
09/01/2007

Date of final enrolment
09/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Neurosurgical Centre Nijmegen
Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
Radboud University Nijmegen (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.nccn.nl

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Other

Funder Name
Insurances will be paid by the Neurosurgical Centre Nijmegen (The Netherlands). All other costs for the trial will be covered by the Principal Investigator. If financial sponsors are found, these costs will be settled.

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	09/11/2007		Yes	No