

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

Submission date 13/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name
Dr Ronald Bartels

Contact details
Neurosurgical Centre Nijmegen
Radboud University Nijmegen
Nijmegen
Netherlands
6500 HB
+31 (0)24 361 3447
r.bartels@nch.umcn.nl

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

Department of Neurosurgery

R. Postlaan 4

Nijmegen

Netherlands

6500 HB

+31 (0)24 361 3477

r.bartels@nch.umcn.nl

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