

# Identification of predisposing factors for functional deterioration and kyphosis of the cervical spine after a cervical laminectomy; a cohort study.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Spinal cord and nerve root disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON33459

### Source

ToetsingOnline

### Brief title

The clinical results of the cervical laminectomy.

### Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

### Synonym

kyphosis of the CWK & independence of the patient

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cervical, kyphosis, spine, stenosis

## Outcome measures

### Primary outcome

The primary outcome parameter is the functionality of the patient that is established by scoring this functionality on several different validated scales. For the group as a whole, including those patients who are lost to follow up, the scales will be the Odom and the Likert scale.

For those patients in whom follow up study is possible, the outcome will be established with a combination of the Odom and Likert scale, the Nurick score, the adjusted Japanese Orthopedic Association (JOA) score, the Cooper Myelopathy Scale (CMS), the European Myelopathy Score (EMS) and the Myelopathy Disability Index (MDI).

Another primary outcome parameter is the presence of kyphosis of the cervical spine, which will be determined by comparing the pre- and postoperative X-ray of the cervical spine using the Batzdorf classification and the Matsumoto method. Not only the presence of kyphosis, but also the degree of kyphosis will be measured.

### Secondary outcome

A secondary outcome parameter is the instability of the cervical spine after a

cervical laminectomy. Instability will be measured on functionality X-rays of the cervical spine on the follow up visit of the patient. Instability will be determined by considering the alignment of the posterior borders of the corpora.

## Study description

### Background summary

Degenerative changes of the cervical spine often result in clinical symptoms, like for instance neurological deficits, because these degenerative changes result in compression of the spinal cord. In earlier years, a wait-and-see policy was generally advocated. If eventually a decompression was inevitable the posterior approach was chosen. In the eighties an anterior approach became more popular, even for a decompression of more than one level. However, an anterior discectomy of more levels implies at least one corporectomy and thus a surgical procedure including a spondylodesis. This leads to loss of mobility of the cervical spine. Moreover, the patient wears a stiff collar for several months, which many patients consider uncomfortable. Finally, the risk of dysphagia and dysphonia is considerable in anterior decompressive surgical procedures involving corporectomies.

In daily practice, satisfying results are accomplished using the posterior approach to decompress the cervical spinal cord. In current publications though, this approach is considered to be outdated, since it would lead to kyphosis and instability of the cervical spine. This would ultimately lead to new or recurrent clinical symptoms of spinal cord compression.

It is however insufficiently examined whether a cervical laminectomy indeed results in kyphosis and instability and it was never investigated whether and to which extent kyphosis and/or instability cause clinical symptoms. Therefore a study that studies these aspects is deemed necessary.

### Study objective

The primary goal of this study to investigate the long term functional and radiological outcome of those patients that underwent a cervical laminectomy in the treatment of a cervical spondylotic myelopathy.

The secondary goal is to determine those factors that have a significant influence on 1) deterioration in functionality and 2) kyphosis of the cervical spine after a cervical laminectomy.

### Study design

A retrospective patient file investigation in those patients that had a cervical laminectomy between 1994 and 2005 in combination with a follow up evaluation (both anamnestic and radiological) of the current situation of those same patients

### **Study burden and risks**

The patient has to come to the hospital only one time to fill in questionnaires and on this same day three X-rays of the cervical spine will be made.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

cervical laminectomy between 1994-2005  
clinical symptoms correspond with a cervical myelopathie  
informed consent

## Exclusion criteria

no MRI and x-CWK before surgery  
has had any additional surgery of the cervical spine  
no follow-up after surgery

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2009

Enrollment: 200

Type: Actual

## Ethics review

Approved WMO

Date: 13-08-2009

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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
CCMO	NL27566.058.09