# The clinical results of the cervical laminectomy.

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Failing in the functionality of patients, who underwent a cervical laminectomy, isn't relate to kyphosis of the cervical spine.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON21794

**Bron**
NTR

**Verkorte titel**
N/A

**Aandoening**

kyphosis of the CWK & independence of the patient

abnormale kromming van de wervelkolom & mate van functioneren van de patient

### Ondersteuning

**Primaire sponsor:** N/A
**Overige ondersteuning:** N/A

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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.<br>
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).
<br><br>
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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

Failing in the functionality of patients, who underwent a cervical laminectomy, isn't relate to kyphosis of the cervical spine.

### Onderzoeksopzet

The patient wil come to the hospital only for one time.

### Onderzoeksproduct en/of interventie

N/A

## Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Cervical laminectomy between 1994-2005;

2. Clinical symptoms correspond with a cervical myelopathie;

3. Informed consent.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No MRI and x-CWK before surgery;

2. Has had any additional surgery of the cervical spine;

3. No follow-up after surgery.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-07-2009 |
| Aantal proefpersonen: | 200 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 16-04-2010 |
| Soort: | Eerste indiening |

## Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2172 |
| NTR-old | NTR2296 |
| Ander register | METC Leids Universitair Medisch Centrum : P09.104 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A