The clinical results of the cervical laminectomy.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21794

Source
Nationaal Trial Register

Brief title
N/A

Health condition

kyphosis of the CWK & independence of the patient

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

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

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 secundary 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

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

Study design

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

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Cervical laminectomy between 1994-2005;

2. Clinical symptoms correspond with a cervical myelopathie;

3. Informed consent.

Exclusion criteria

1. No MRI and x-CWK before surgery;

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

3. No follow-up after surgery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-04-2010
Application type:	First submission

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
NTR-new	NL2172
NTR-old	NTR2296
Other	METC Leids Universitair Medisch Centrum : P09.104
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A