# Effectiveness of surgery versus prolonged conservative care in patients suffering from a herniated cervical disc

Published: 02-05-2012
Last updated: 15-05-2024

It is required to compare results from conservative- and surgical treatment in The Netherlands and to perform an economic evaluation in order to evaluate the cost-effectivity of both treatment types. On one hand, surgical treatment seems accompanied...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON46954

**Source**
ToetsingOnline

**Brief title**
CASINO

### Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

**Synonym**
radicular arm pain; cervical disc herniation

**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:** Anterior discectomy, Cervical radicolopathy, Cost effectiveness, Nonsurgical treatment, Utility analysis

## Outcome measures

### Primary outcome

Measurements will take place at 6 weeks, 3, 6, 9, 12 and 24 months. The primary outcome is the VAS score for arm pain.

### Secondary outcome

Secondary outcome is the timing of surgery in according the duration of the symptoms.

Secondary parameters are the LCRSF (Leiden CRS Functioning Scale) VAS neck pain, perceived recovery (Likert), SF36, EuroQol, VAS quality of life, IPQ-K, DS-14, WOMAC, MRI findings, re-operation frequency, and cost diaries. The economical evaluation will be a cost utility analysis from a societal perspective, based on patient reports.

# Study description

### Background summary

The cervical radicular syndrome (CRS), being caused by a cervical hernis nuclei pulposi (HNP), is a frequently occuring problem. The CRS causes radiating pain in the arm, and often has an intensity that prohibits normal functioning. Apart from that, motor and/or sensory deficits can accompany this pain. In the

majority of patients with these complaints, the symptons gradually diminish within weeks to such an extent that the normal way of live can be continued. If however the complaints do not diminish spontaneously, or not within reasonable time, the patient will be referred to the neurologist and subsequently to the neurosurgeon to judge a surgical intervention. The surgical intervention consist a discectomy, at which the bulging part of the disc, compressing the spinal root, can be taken out.
CRS is a disease for which both conservative therapy and surgical therapy could provide a good result. However, it is unknown whether early neurosurgical intervention or prolonged conservative care is more effective or more cost-effective. In the present study, the effectiveness of timing of the anterior discectomy will be studied. This investigation concerns an intervention that is considered to be 'usual care' of which the timing is under discussion.

## Study objective

It is required to compare results from conservative- and surgical treatment in The Netherlands and to perform an economic evaluation in order to evaluate the cost-effectivity of both treatment types. On one hand, surgical treatment seems accompanied by high costs, but also by less absenteeism, compared to prolonged conservative care.

This allows for formulation of the following research question:

Primary question:
What is the effect of choosing conservative care vs surgical treatment on clinical parameters one and two years after follow-up?

Subquestions:
- Which factors identify patients choosing for a specific treatment type?
- Are these identifying factors after one- and two years follow-up comparable in both groups?
- Is there a difference between patients undergoing early- vs late surgery?
- Value based health care: is there a difference in cost-effectiveness between groups (conservative vs. early surgery vs. surgery)?

## Study design

The present project is a prospective study with two-year follow-up and repeated measurements. Patients are eligible for inclusion between ages 18-75, with persisting cervical radicular syndome for more than two months. The Leiden University Medical Center will provide as data coordination center. Here, data will be collected, analyzed and preserved.

## Intervention

In both arms of the study the treatment is according to *usual care*.

This means for the conservative group mainly pain medication. In order to let patients maintain their conservative treatment it is important to reduce anxiousness of the patients and repeated explanations on the gunstige prognosis of the CRS. It is not usual to prescribe a soft collar and/or fysiotherapy to patients suffering from a CRS, but when the family doctor deems this preferable to the begeleding van de patient it can be prescribed.

Patients in the surgery group will be operated within 4 weeks. The surgeon is free to use the manner he/she likes, as long as it is filled in on a standaard way.

**Study burden and risks**

Participation in the present study does not a special risk.

# Contacts

**Public**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
**Scientific**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- Age 18-75 years
- Cervical radicular syndrome in one arm for at least 2 months
- Radiographic diagnosis of cervical disc herniation
- Informed consent

### Exclusion criteria

- Signs of myelopathy
- Severe paresis (MCR <= 3)
- Cervical spine surgey in the past
- Instability of the cervical spinal column requiring stabilisation
- Pregnancy
- Severe life-threatening or psychiatric illness
- Insufficient knowledge of Dutch language
- Planned emigration in the year after randomization

## Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-05-2012 |
| Enrollment: | 200 |

| | |
|---|---|
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 02-05-2012 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 11-06-2012 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 26-07-2012 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 21-01-2013 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

| | |
|---|---|
| Approved WMO Date: | 10-04-2013 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

Approved WMO

Date: 01-05-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 17-07-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 02-09-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 01-10-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 11-02-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 04-03-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 15-04-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 12-06-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 23-07-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 02-12-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 02-02-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO
Date: 24-11-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

| | |
|---|---|
| Date: | 27-06-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 26186
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL39403.058.12 |
| OMON | NL-OMON26186 |