

Cervical rAdiculopathy; Surgical or NOnsurgical treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26186

Source

Nationaal Trial Register

Brief title

CASINO

Health condition

Cervical radiculopathy, utility analysis, nonsurgical treatment, cost-effectiveness, discectomy.

cervicaal radiculair syndroom, utiliteitsschaal, niet-operatieve behandeling, kosteneffectiviteit, discectomie.

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)

Source(s) of monetary or material Support: ZonMw, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

VAS arm pain.

Secondary outcome

The timing of surgery in according the duration of the symptoms.

1. VAS neck pain;
2. perceived recovery;
3. SF36;
4. EuroQol;
5. VAS qyality of live;
6. IPQ-K;
7. DS-14;
8. MRI findings;
9. Re-operation frequency;
- 10.cost diaries.

The economical evaluation will be a cost utility analysis from a societal perspective, based on patient reports.

Study description

Background summary

The primary purpose of this study is to investigate whether arm pain due to a cervical HNP that existed for at least two months can be considered a self-limiting disease and therefore treated conservatively and whether the outcome is comparable to surgical intervention. The analysis will lead to a trade-off between less direct costs in the conservative group on the one side and on the other side early recovery of arm pain in the surgery group, leading to less indirect costs. The conservative group misses the costs of a surgical intervention and the risk of the risk of the surgeon, but may suffer from chronic pain in the arm. An economic evaluation will be part of the study. This leads to the following research questions with regard to patients with a cervical radicular syndrome caused by a hernia nucleus pulposus: 1. Is a policy of prolonged conservative care sometimes followed by 'late' surgery more (cost-) effective than 'early' surgery in patients with a cervical radicular syndrome that is present for

at least two months? We will also study the following secondary research question: 2. Is there a relation between the duration of symptoms at baseline and the relative effect of surgery compared to conservative treatment on the outcome after one year of follow up after randomization.

This study is a multi-centre comparative randomized clinical trial with parallel group design. The follow up is at least two years. Participation to this trial will be asked at all patients (18-65 jr.), that have radicular arm pain which exists for at least two months and is not in a phase that the pain already diminishes. The MRI has to demonstrate a HNP which compresses the nerve root that corresponds to the clinical symptoms of the patient. These patients can enroll in the study, if they apply to all the inclusion criteria and do not apply to the exclusion criteria.

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 favourable prognosis of the CRS. It is not usual to prescribe a soft collar and/or physiotherapy to patients suffering from a CRS, but when the family doctor deems this preferable to the counseling of the 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 standard way.

Outcome measures will be reported at 6 weeks, 3, 6, 9, 12 and 24 months. The primary outcome is the VAS arm pain.

Secondary outcome is the timing of surgery in according the duration of the symptoms. secondary parameters are VAS neck pain, perceived recovery (Likert), SF36, EuroQol, VAS quality of life, IPQ-K, DS-14, MRI findings, reoperation frequency, and cost diaries. The economical evaluation will be a cost utility analysis from a societal perspective, based on patient reports.

Study objective

Prolonged conservative care, sometimes followed by 'late' surgery, is more (cost-)effective than 'early' surgery in patients with a cervical radicular syndrome that is present for at least two months.

Study design

Written questionnaires at initial visit, at 2, 4, 6, 12, 26, 38,52 and 104 weeks after the first visit.

Outpatient clinic physical examination at initial visit and at 6, 26,52 and 104 weeks after the first visit.

Intervention

A 6 months prolonged conservative treatment approach with counseling by the general practitioner, prescription of analgesics and eventually delayed surgery in a smaller population of patients with persisting complaints.

The control group will receive physiotherapy, a soft collar and analgesics if desired, possibly followed by surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-75 years;
2. Cervical radicular syndrome in one arm for at least 2 months;
3. Radiographic diagnosis of cervical disc herniation;

4. Informed consent.

Exclusion criteria

1. Signs of myelopathy;
2. Severe paresis ($MCR \leq 3$);
3. Cervical spine surgery in the past;
4. Instability of the cervical spinal column requiring stabilisation;
5. Pregnancy;
6. Insufficient knowledge of dutch language;
7. Planned emigration in the year after randomization.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2012
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date: 03-07-2012

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46954

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3356
NTR-old	NTR3504
CCMO	NL39403.058.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON46954

Study results

Summary results

N/A