Cervical rAdiculopathy; Surgical or NOnsurgical treatment.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26186

Bron
Nationaal Trial Register

Verkorte titel
CASINO

Aandoening

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

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: ZonMw, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

VAS arm pain.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Signs of myelopathy;

2. Severe paresis (MCR≤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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2012
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46954
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A