Comparison of cost-effectiveness between two surgical procedures (anterior or posterior decompression) in patients with cervical nerve root entrapment

No registrations found.

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

Summary

ID

NL-OMON24269

Source
NTR

Brief title
FACET

Health condition

English: cost-effectiveness, radiculopathy, foraminotomy, discectomy, randomized controlled trial, cervical spine

Dutch: kosten-effectiviteit, radiculopathie, foraminotomie, discectomie, randomized controlled trial, cervicale wervelkolom

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development (in Dutch "ZonMW")

Intervention

Outcome measures

Primary outcome

The main study parameter is to compare the clinical outcome (decrease in radiculopathy assessed by (Visual Analogue Scale for self-reported brachialgia) between patients operated with the FOR technique or with the ACDF technique during 24 months of follow up, this will be defined as “operative success”. "Patient success” will be defined through the ODOM’s criteria.

Secondary outcome

1. Changes in work ability (Work Ability Index, single item) during 24 months of follow up between the two groups.

2. Changes in quality of life (EQ-5D) during 24 months of follow up between the two groups.

3. Changes in neck pain (VAS) during 24 months of follow up between the two groups .

4. Changes in Neck Disability Index (NDI) during 24 months of follow up between the two groups .

5. Number or percentage of complications in the short (30 days) and long term period (104 weeks) between the two groups

6. Cost-effectiveness (104 weeks)

7. Budget impact (extrapolated to 5 years)

Study description

Study objective

Disability due to cervical radiculopathy has a significant impact on the patient’s quality of life, particularly because most patients participate in the community’s labour force. Cervical radiculopathy due to discogenic or spondylotic stenosis of the neuroforamen can be surgically treated by an anterior discectomy with fusion (ACDF) or a posterior foraminotomy (FOR). Currently, there are no evidence-based guidelines on the most appropriate surgical treatment strategy. In the Netherlands, there is a surgeon’s preference for ACDF. However, there is evidence that FOR is as effective as ACDF, has a smaller complication rate and is less expensive. The study objectives of the FACET study are to compare clinical outcome

(decrease of radiculopathy in VAS ARM pain and Odom's criteria), complication rates, cost-effectiveness and work absenteeism with a non-inferiority hypothesis of FOR to ACDF.

Study design

Timepoint 1: Baseline evaluation after informed consent is signed

- Medical and preoperative history

- Clinical evaluation (signs, symptoms, strength, reflexes)

- Web based patient self-assessment (questionnaires: arm pain VAS, neck pain VAS, WAI, EQ-5D, NDI, iMCQ, iPCQ)

Timepoint 2: Surgical Procedure (FOR or ACDF), following standard care protocol.

- Surgical evaluation report (date, type, antibiotic prophylaxes, level of procedure, instruments, complications and (S)AE’s).

Timepoint 3: Day of discharge

- Clinical evaluation (signs, symptoms, strength, reflexes)

- Odom’s criteria

Timepoint 3.1-3.5: 1 week till 5 weeks after discharge; weekly assessment of arm and neck pain VAS (web based)

Timepoint 4: 6 weeks after operation (± 1 week) (at outpatient clinic)

- Clinical evaluation (signs, symptoms, strength, reflexes)

- Odom’s criteria

- Web based patient self-assessment on pain, quality of life and costs (questionnaires: arm pain VAS, neck pain VAS, WAI, EQ-5D, NDI, iPCQ, iMCQ)

Timepoint 5: 26 weeks after operation (± 2 weeks) (patients do not attend the hospital)

- Web based patient self-assessment on pain, quality of life and costs (questionnaires: arm pain VAS, neck pain VAS, WAI, EQ-5D, NDI, iPCQ, iMCQ)

- Odom’s criteria (patients will be contacted by telephone, by an independent interviewer, to evaluate the ODOM’s criteria)

Timepoint 6: 52 weeks after operation (± 4 weeks) (patients do not attend the hospital)

- Web based patient self-assessment on pain, quality of life and costs (questionnaires: arm pain VAS, neck pain VAS, WAI, EQ-5D, NDI, iPCQ, iMCQ)

- Odom’s criteria (patients will be contacted by telephone, by an independent interviewer, to evaluate the ODOM’s criteria)

Timepoint 7: 78 weeks after operation (± 4 weeks) (patients do not attend the hospital)

- Web based patient self-assessment on pain, quality of life and costs (questionnaires: arm pain VAS, neck pain VAS, WAI, EQ-5D, NDI, iPCQ, iMCQ)

- Odom’s criteria (patients will be contacted by telephone, by an independent interviewer, to evaluate the ODOM’s criteria)

Timepoint 8: 104 weeks after operation (± 4 weeks) (patients do not attend the hospital)

- Web based patient self-assessment on pain, quality of life and costs (questionnaires: arm pain VAS, neck pain VAS, WAI, EQ-5D, NDI, iPCQ, iMCQ)

- Odom’s criteria (patients will be contacted by telephone, by an independent interviewer, to evaluate the ODOM’s criteria)

During the complete study period, adverse events and serious adverse events will be reported.

Intervention

ACDF technique:

Microsurgical discectomy is performed through a ventral approach described by Smith and Robinson (1958). Procedure can be executed with microscope or loupe magnification. Exploration of the intervertebral disc and removal of bony spurs with a high-speed drill.

Removal of the posterior part of the intervertebral space. The posterior ligament is dissected and removed with rongeurs. Subligamentous discal fragments are removed. The proximal part of the neuroforamen is inspected for discal remnants. If an osteophytic component is present, the uncovertebral joint is reduced to remove the osteophytic component. An intervertebral spacer is placed to keep height of the intervertebral disc space. No additional plate fixation is used.

FOR technique:

All patients are operated in prone position with the head fixated in a 3-point head holder. After determining the correct level on lateral radiograph, a vertical 4 cm midline incision is made, and the lateral lamina/medial facet joints are exposed. A retractor is placed adequately. Under the operating microscope or loupe magnification and after a second confirmation of the correct level, a partial hemi-laminectomy and foraminotomy with partial factectomy of the involved level is performed with high-speed drills. The percentage of the facet resection is based on the extent of the foraminal pathology. In cases of pure soft discs, the proximal root is visualized adequately for removal of the compressing disc material. In cases of foraminal stenosis, bony decompression and skeletonization of the proximal root are performed carefully using a 4-mm diamond burr, small rongeurs, and dissectors.

Contacts

Public
Department of Neurosurgery - University Medical Center Groningen

J.M.A. Kuijlen
Postbus 30.001

Groningen 9700RB
The Netherlands
T: 0031503617976
Scientific
Department of Neurosurgery - University Medical Center Groningen

J.M.A. Kuijlen
Postbus 30.001

Groningen 9700RB
The Netherlands
T: 0031503617976

Eligibility criteria

Inclusion criteria

- Age between 18 and 80 years.

- Cervical foraminal stenosis due to a soft disc component causing monoradiculopathy of C4, C5, C6, or C7 and requiring decompression of neuroforamen. (Foraminal stenosis due to a soft disc component is defined as: 2/3 of the total discal component is located intraforaminally and a maximum of 1/3 of the total discogenic component is located medially, within the spinal canal. Radiculopathy is defined as pain, paresis or paresthesia in corresponding nerve root distribution areas of C4, C5, C6,or C7,and must include at least arm or shoulder pain with minimum of 30 mm on a 100 mm visual analog scale).

- No response to conservative treatment for eight weeks or presence of progressive symptoms or signs of nerve root compression in the face of conservative treatment.

- Soft disc/Spondylotic foraminal stenosis (determined by MRI, CT or an oblique X-ray of the cervical spine) at the treatment level correlating to primary symptoms.

- Psychosocially, mentally, and physically able to fully comply with this protocol, including adhering to scheduled visits, treatment plan, completing forms, and other study procedures.

- Patient has sufficient mastery of the Dutch language to fill out the questionnaires.

- Signed and dated informed consent document prior to any study-related procedures

Exclusion criteria

- Multisegmental CRS.

- Median located disc protrusion or osteophytic protrusion.

- Foraminal compression of C8.

- Spinal cord compression with clinical myelopathy.

- Radiological myelopathy.

- History of cervical spine surgery.

- Malignant obesity (BMI > 30).

- Osteoporosis / chronic use of corticosteroids.

- ASA 4 and 5 patients (serious ill patients).

- Pregnancy

- Active malignancy

- Abundant use of alcohol, drugs, narcotics and recreational drugs.

- Contra-indications for anesthesia or surgery

- Patient has used another investigational drug or device within the 30 days prior to surgery

- Incapability to speak and write the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2015
Enrollment:	308
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-11-2015

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47024
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5419
NTR-old	NTR5536
CCMO	NL54380.042.15
OMON	NL-OMON47024

Study results