ISRCTN82578069 https://doi.org/10.1186/ISRCTN82578069

Comparison of two surgical approaches to decompress bony spurs compressing the spinal nerve at the opening of the cervical spinal canal

Submission date
02/11/2013

Recruitment status
No longer recruiting

Registration date
25/11/2013

Overall study status
Completed

Last Edited
10/11/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Degenerative conditions of the cervical spine can include bony spurs (tiny pointed outgrowths of bone) that narrow the opening where the spinal nerves leave the spinal canal. This can cause radiating pain and unpleasant feelings in the arms and hands. The surgical options to remove these bony spurs include a surgical approach from the front side of the neck and a surgical approach from the back side of the neck. There is a controversy regarding which is the best surgical approach. Treatment decisions are determined mostly by the individual surgeons preference and skill. The aim of this study is to evaluate the effectiveness and safety of these two surgical approaches.

Who can participate?
Male and females between 18 and 80 years of age with radiating pain or discomfort in the arm and/or hand due to bony spurs at the opening for the spinal nerves in the cervical spine.

What does the study involve?
The participants will be randomly allocated to one of two surgical options to remove the bony spurs: either a surgical approach from the front side of the neck or a surgical approach from the back side of the neck. The participants of the study will be followed-up after 3, 6 and 12 months and then yearly for the next 4 years.

What are the possible benefits and risks of participating?
Participation in the study does not result in specific benefits for the patient. Both surgical approaches under investigation are well-established techniques in clinical practice and can be performed with comparable low risk. Surgery from the front side of the neck includes risks of injury of cervical organs and vessels. Moreover, placement of an intervertebral fusion cage might potentially result in implant dislocation. Specific risks of the surgical approach from the back side of the neck are advancing degeneration of the affected level and progressive deformity of the neck.

Where is the study run from?
The study is run from the Department of Neurosurgery, Innsbruck Medical University in Austria, the Department of Neurosurgery, LKH Feldkirch, Austria and the Department of Neurosurgery, University Medical Center Mannheim, Heidelberg University, Germany.

When is the study starting and how long is it expected to run for?
The study started in June 2013 and is expected to run for 7 years.

Who is funding the study?
German Spine Foundation (Germany).

Who is the main contact?
PD Dr. med. Aldemar Andres Hegewald
aldemar.hegewald@medma.uni-heidelberg.de

Contact information

Type(s)
Scientific

Contact name
Dr Aldemar Andres Hegewald

Contact details
Department of Neurosurgery
University Medical Center Mannheim, Heidelberg University
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167
aldemar.hegewald@medma.uni-heidelberg.de

Additional identifiers

Study information

Scientific Title
Comparison of posterior Foraminotomy and anterior foraminotomy with fusion for treating spondylotic foraminal stenosis of the Cervical spine: a randomized clinical trial

Acronym
ForaC

Study objectives
The purpose is to evaluate efficacy and safety of posterior foraminotomy in comparison to anterior foraminotomy with fusion for the treatment of spondylotic foraminal stenosis.
H0: There is no difference in the mean neck disability index between posterior and anterior foraminotomy at five years follow-up.
HA: There is a difference in the mean neck disability index between posterior and anterior foraminotomy at five years follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical University of Innsbruck (Ethikkommission der Medizinischen Universität Innsbruck), Date of approval (protocol version 1.0): 04/06/2012, Approval of amendment (protocol version 1.1): 26/04/2013, ref: AM4702

Primary study design
Interventional

Study design
Randomized controlled multi-center study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spondylotic foraminal stenosis of the cervical spine

Interventions
Two surgical interventions will be compared:
1. Posterior foraminotomy
2. Anterior foraminotomy with fusion

One day prior to the surgical intervention patients are randomized to posterior or anterior cervical approach according to the randomization list. Treatment assignment is documented. The randomization process, along with data storage, processing and statistical analysis is performed independently in the Department of Medical Statistics, Informatics and Health Economics of Innsbruck Medical University.

Patients will be followed-up for 5 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Neck Disability Index (NDI) at five years follow-up

Key secondary outcome(s)
1. Core Outcome Measures Index (COMI)
2. Individual patient success at 12, 24, 36 and 60 months consisting of:
2.1. Improvement of at least 17 in the NDI (100 points) compared to baseline (adjustable according to results from own MCIC results for NDI)
2.2. Pain relief, as defined by ≥20 mm improvement on 100 mm VAS for arm/shoulder pain
2.3. Global outcome (1 or 2 on five-category Likert scale)
2.4. No opiates or opiate derivatives because of neck and/or arm pain

2.5. Absence of symptomatic device failure and re-operations at the index level
3. Pain relief, as defined by ≥20 mm improvement on 100 mm VAS for neck pain and arm /shoulder pain
4. Changes in physical and mental health defined as improvement of 15% in the overall score as captured by the SF-12v2
5. Modified Japanese Orthopedic Association (mJOA) score and Nurick score
6. Adjacent level degeneration:
6.1. By evidence of instability, defined as sagittal plane translation >3.5mm (20% of vertebral body - AP diameter) and/or sagittal plane rotation of >20° based on standing flexion/extension X-rays
6.2. By evidence of disc degeneration (Miyazaki grade ≥ IV) and/or osteochondrosis (Modic change type I) on MRI
6.3. Radiographic classification (Walraevens 0-3)
6.4. By occurrence of operation because of adjacent level disease
7. Quantitative sensory testing
8. Segmental lordosis and overall cervical sagittal alignment
9. Operative time
10. Length of hospital stay
11. Pain medication usage (including epidural injections and nerve block injections)
12. Return to work
13. Worker's compensation
14. Direct and indirect societal costs

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Age between 18 - 80 years
2. Cervical spondylotic foraminal stenosis causing radiculopathy of C5 and/or C6 and/or C7 and requiring decompression of ≤ 2 neuroforaminae
3. Radiculopathy is defined as pain, paralysis or paresthesia in corresponding nerve root distribution areas of C5 and/or C6 and/or C7, and must include at least arm/shoulder pain with minimum of 30 mm on 100 mm visual analogue scale (VAS)
4. Neck Disability Index (NDI) score ≥ 30 out of 100
5. Unresponsive to non-operative treatment for six weeks or presence of progressive symptoms or signs of nerve root compression in the face of conservative treatment
6. Magnetic resonance imaging (MRI) and computerised tomography (CT) determined spondylotic foraminal stenosis at treatment level/levels that correlate to primary symptoms
7. Appropriate candidate for treatment using both an anterior approach via ventral discectomy and fusion or a posterior approach via foraminotomy as described by Frykholm
8. Psychosocially, mentally and physically able to fully comply with this protocol, including adhering to scheduled visits, treatment plan, completing forms and other study procedures
9. Personally signed and dated informed consent document prior to any study-related procedures indicating that the patient has been informed of all pertinent aspects of the trial.

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Clinical criteria:
1. Previous cervical spinal surgery at index level
2. Lumbar or thoracic spinal disease to the extent that surgical consideration is likely or anticipated within 6 months after the cervical surgical treatment
3. Upper extremity degenerative joint diseases (i.e. shoulder) to the extent that:
3.1. Surgical consideration is likely or anticipated within 6 months after the cervical surgical treatment
3.2. The resulting pain is chronic (>3 months)
4. Axial neck pain in the absence of other symptoms of radiculopathy justifying the need for surgical intervention
5. Myelopathy
6. Neoplasia as the source of symptoms
7. Fixed or permanent neurological deficit unrelated to the cervical disc disease
8. Disease or conditions that preclude accurate clinical evaluation (e.g. neuromuscular disorders)
9. Active or chronic infection, systemic or local
10. Systemic disease including HIV, AIDS, hepatitis
11. Active malignancy defined as a history of any invasive malignancy, except non- melanoma skin cancer, unless the patient has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for a minimum of 5 years
12. Pagets disease, osteomalacia, or any other metabolic bone disease (for osteoporosis see below)
13. Autoimmune disorder that impacts the musculoskeletal system (i.e. lupus, rheumatoid arthritis, ankylosing spondylitis)
14. Acute episode or major mental illness (psychosis, major affective disorder or schizophrenia)
15. Physical symptoms without a diagnosable medical condition to account for the symptoms, which may indicate symptoms of psychological rather than physical origin
16. Recent or current history of substance abuse (drugs, alcohol, narcotics, recreational drugs)
17. Anticipated long-term use of systemic steroid medications postoperatively

Radiological criteria:
1. A symptomatic spondylotic foraminal stenosis - considered for surgical intervention, with a contralateral asymptomatic spondylotic foraminal stenoses at the same level with equal or higher extent in the CT exams
2. Cervical disc herniation or central canal stenosis causing radiculopathy or clinical myelopathy
3. Myelopathy in the MRI exams
4. Marked cervical instability on flexion/extension radiographs defined as: Translation > 3mm and /or Angulation > 20°
5. Kyphotic segmental angulation >11° at treatment or adjacent levels

Varia (Other):
1. Patient is currently pursuing personal litigation related to spinal diseases
2. Prisoner or ward of the state
3. Patient has used another investigational drug or device within the last 30 days prior to surgery

Date of first enrolment
01/06/2013

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Department of Neurosurgery
Mannheim
Germany
68167

Sponsor information

Organisation
Innsbruck Medical University (Austria)

ROR
https://ror.org/03pt86f80

Funder(s)

Funder type
Research organisation

Funder Name
German Spine foundation (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/11/2014		Yes	No