ISRCTN16571565 https://doi.org/10.1186/ISRCTN16571565

Trial to investigate which treatment is preferred for mild symptoms due to stenosis (narrowing) in the cervical spinal canal: conservative treatment or surgery

Submission date
11/11/2021

Recruitment status
No longer recruiting

Registration date
01/02/2022

Overall study status
Ongoing

Last Edited
01/02/2022

Condition category
Nervous System Diseases

[X] 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
Due to the ageing of the population more people will suffer from complaints and signs related to degeneration of the cervical spine (the neck region of the spine). The spinal cord may be involved, causing a loss of dexterity, walking difficulties, and even urination problems. If the clinical situation is severe, surgery will be offered to decompress the spinal cord. The goal is to maintain and hopefully improve the clinical situation. For less severe (mild) situations the best treatment is less clear. Conservative treatment and surgery are both valid options, although it may be argued that surgery will be more beneficial in the end. The aim of this study is to find out whether surgical decompression is more beneficial than conservative treatment for mild cervical spondylotic myelopathy (CSM) - a compression of the spinal cord in the neck.

Who can participate?
Adult patients with mild signs and symptoms due to compression of the spinal cord and degeneration of the spinal canal.

What does the study involve?
Participants are randomly allocated to either receive conservative treatment or undergo surgical decompression. For conservative treatment participants are referred to a physical therapist to practice hand function and improve their walking abilities. Participants are assessed at the start of the study and after 6 weeks, 3, 12 and 24 months

What are the possible benefits and risks of participating?
Since both treatments are standard in daily clinical practice, there are no additional benefits are risks for the participants.

Where is the study run from?
Radboud University Nijmegen Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
August 2021 to June 2027

Who is funding the study?
Application for grant awaiting approval

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CCMO 2021-13141

Study information

Scientific Title
COnservative or SUrgical treatment for mild cervical spondylotic myelopathy: a multi-center randomized controlled trial

Acronym

COSU

Study objectives
The primary objective of this study is to investigate whether surgical decompression is more beneficial than conservative treatment in cases of mild cervical spondylotic myelopathy (CSM). The second objective is to evaluate whether surgery is cost-effective compared with conservative treatments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, METC Oost Nederland (p/a Radboudumc, huispost 628, Postbus 9101, 6500 HB Nijmegen, Netherlands; +31 (0)24 361 3154; metcoost-en-cmo@radboudumc.nl) ref: Dossiernummer: 2021-13139, NL-nummer: NL78934.091.21

Study design
Multi-center randomized controlled trial with an additional economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Cervical spondylotic myelopathy

Interventions
For the treatment group allocation, a variable block randomization method is chosen. For this purpose, an online data system, CastorEDC (EU HQ, Amsterdam, the Netherlands), is used. Variable block sizes of four, six, and eight will be used and stratified by treatment center. Patients will be randomized in a 1:1 ratio to conservative treatment or surgical decompression. The randomisation sequence was generated by an independent statistician. Each patient will be given a unique study number. The web-based system will be supervised by the Clinical Trial Center of Radboud university medical center. Randomization will take place after the patients provide informed consent to participate. A designated member of the site team, usually a clinician or nurse involved in the participant's care, did the online randomization.

Surgery:
The goal of surgical intervention is the decompression of the spinal cord to halt the progression of the disease and facilitate recovery. Several approaches are possible: laminectomy with or

without fusion, laminoplasty with or without fusion, anterior discectomy with fusion, corpectomy, or a circumferential approach. None of them has been proven superior. The choice of approach is dependent upon the levels of compression, the shape of the cervical spine, instability of the cervical spine, and also the preference of the surgeon; therefore, the surgical approach is at the discretion of the treating surgeon.

Conservative treatment:
Supervised conservative therapy will also be used. The patients are referred to a physical therapist to practice hand function and improve their walking abilities. During the study, the patients are contacted via video calls to evaluate their clinical condition. If the symptoms and signs worsen, the patients are invited to the outpatient clinic. A physical examination is performed, and surgical decompression may be offered as treatment if the neurologic condition worsens or if the patient's conviction is altered during the course of the treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Functionality of the hand is measured using the 15-s grip and release test at baseline, 6 weeks, 3, 12 and 24 months

Secondary outcome measures
1. Disability is measured by the modified Japanese Orthopaedic Association (mJOA) score at baseline, 3, 12 and 24 months
2. Neck pain and disability due to neck related problems is measured by the neck disability index (NDI) at baseline, 3, 12 and 24 months
3. Quality of life is assessed by the EQ-5D-5L at baseline, 3, 12 and 24 months
4. Complications are registered in the early postoperative stage (6 weeks)
5. Healthcare resource use is measured by the iMTA Medical Consumption Questionnaire (iMCQ) at baseline, 3, 12 and 24 months
6. Productivity loss is assessed by the iMTA Productivity Cost Questionnaire (iPCQ) at baseline, 3, 12 and 24 months

Overall study start date
29/08/2021

Completion date
01/06/2027

Eligibility

Key inclusion criteria
1. Adult patients
2. Signs and symptoms of cervical myelopathy
3. Radiologic signs of degenerative compressive cervical myelopathy
4. mJOA ≥15

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Non-fluent in the Dutch language
2. Soft disc as causative pathological mechanism
3. Coexisting diseases that cause signs and symptoms interfering with those of CSM, e.g., plexopathy, cerebrovascular incident, polyneuropathy due to diabetes mellitus, etc
4. Alcohol abuse (more than two units daily)
5. mJOA <15
6. Previous history of neck surgery
7. Non-degenerative CSM

Date of first enrolment
01/12/2022

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud University Medical Centre
Geert Grote Plein Zuid 10
Nijmegen
Netherlands
6525GA

Study participating centre
Canisius Wilhelmina Ziekenhuis
Weg door Jonkers 100
Nijmegen
Netherlands
6532SZ

Study participating centre

Rijnstate Hospital
Wagnerlaan 55
Arnhem
Netherlands
6815 AD

Study participating centre
Sint Maatenskliniek
Hengstdal 3
Ubbergen
Netherlands
6574 NA

Study participating centre
Leiden University Medical center
Albinusdreef 2
Leiden
Netherlands
2333 ZA

Study participating centre
Haaglanden Medical Center
Lijnbaan 32
The Hague
Netherlands
2512 VA

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

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Sponsor type

Hospital/treatment centre

Website
https://www.radboudumc.nl/EN/Pages/default.aspx

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Other

Funder Name
Application for grant awaiting approval

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2028

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/11/2021	No	Yes
Protocol file	version 2	12/11/2021	25/11/2021	No	No