

# Optimizing treatment in Cervical Radiculopathy;a long term-evaluation of an observational cohort study comparing surgical and conservative treatment

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Het onderzoeken van de klinische en radiologische resultaten op lange termijn van de chirurgische versus conservatieve behandeling van CRS.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON57400

### Source

ToetsingOnline

### Brief title

Optimizing treatment in CRS

### Condition

- Joint disorders
- Spinal cord and nerve root disorders

### Synonym

cervical radicular syndrome, neck herniating disc

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Eurospine. in combinatie met researchfonds Neurochirurgie LUMC

## Intervention

**Keyword:** cervical radiculopathy, patient counselling, prediction modelling

## Outcome measures

### Primary outcome

NDI (clinical parameter)

Fusion, degeneration and sagittal balance (radiological parameters)

### Secondary outcome

VAS arm pain, VAS neck pain, EQ-VAS, WOMAC (to assess arthrosis), Leiden CRIS

(newly developed outcome scale focusing on CRS), DS-14 (personality score)

## Study description

### Background summary

Cervical Radicular Syndrome, a condition often caused by a herniated disc compressing or irritating a nerve root, leads to significant pain and functional impairment in affected individuals. In most cases, the pain and disability due to disc herniations resolve spontaneously over time, or are successfully relieved by a surgical approach. However, in some cases, symptoms remain even after surgery. There is currently no golden standard for the management of cervical radicular syndrome. This highlights the limited knowledge in our understanding of optimal management strategies for this condition.

In efforts to optimize treatment, we previously conducted a multi-centre observational cohort study comparing surgical and conservative treatments, the CASINO trial. The one year follow-up results revealed no significant differences among the two treatment arms. However, at the two year mark, patients who underwent surgical treatment demonstrated promising improvements, particularly in terms of arm and neck pain relief, in comparison to the conservative arm. These findings suggest that surgical intervention may offer superior outcomes over a longer time period, yet the long term implications of these results remain uncertain.

## Study objective

Het onderzoeken van de klinische en radiologische resultaten op lange termijn van de chirurgische versus conservatieve behandeling van CRS.

## Study design

Patients that were formerly included will be asked to return for follow-up assessments, including Patient-Reported Outcome Measures and radiological evaluations. We will examine overall well-being (several parameters) as well as fusion, degeneration and sagittal balance parameters on neutral and dynamic X-rays of the cervical spine.

## Study burden and risks

Patients will be asked to fill in online questionnaires (one timepoint) and to visit a nearby hospital to have X-rays of the cervical spine.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

participants of CASINO trial

### Exclusion criteria

none

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2025

Enrollment: 141

Type: Anticipated

## Ethics review

Approved WMO

Date: 03-04-2025

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

Register	ID
CCMO	NL87765.058.24