

# Evaluation of smoking cessation on the clinical and radiological outcome of instrumented neck- and low back surgery

Published: 23-06-2023

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Objective: To demonstrate that smoking cessation in the postoperative period has a positive impact on the clinical and radiological outcomes of instrumented spine surgery

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Bone disorders (excl congenital and fractures)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON53304

### Source

ToetsingOnline

### Brief title

Stop smoking in spine surgery

### Condition

- Bone disorders (excl congenital and fractures)
- Spinal cord and nerve root disorders

### Synonym

degenerative spine disease, neck- and back problems

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** SGS Achmea

## Intervention

**Keyword:** Fusion, Instrumentation, Smoking, Spine

## Outcome measures

### Primary outcome

Oswestry Disability Index (lumbar spine) of de Neck Disability Index (neck)

### Secondary outcome

VAS leg pain (or arm pain) and VAS back pain (or neck pain), the Hospital

Anxiety and Depression Scale, the EuroQol and the patient's perceived recovery

The bony fusion will be assessed radiologically by CT at 6 and 12 months.

## Study description

### Background summary

Rationale: optimizing outcomes of instrumented neck and back surgery

### Study objective

Objective: To demonstrate that smoking cessation in the postoperative period has a positive impact on the clinical and radiological outcomes of instrumented spine surgery

### Study design

Study design: This is a multicenter observational cohort study with three groups of patients indicated to undergo moderately complex instrumented spinal surgery: a group of patients who continue to smoke is compared with a group who stop smoking. In addition, the results of a group of patients who do not smoke are recorded. Follow-up moments are baseline, 2, 6 and 12 months after surgery.

### Study burden and risks

Stress: stop smoking with the help of the 'SineFuma stop smoking' program and

urine test for nicotine (for those 70 patients who indicate that they want to stop smoking), for all 210 patients: complete a set of questionnaires 4 times.  
Risks: No research-induced risks

## Contacts

### Public

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2300 RC  
NL

### Scientific

Leids Universitair Medisch Centrum

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients eligible for instrumented spine surgery (cervical posterior spondylodesis OR lumbar posterior spondylodesis) due to a degenerative cause.

Patients are between 18 and 75 years old

Patients master the Dutch language

Patients must be cleared for surgery by the anesthesiologist

To be eligible for the 'stop smoking' part, the patient must classify himself

as a 'smoker'

## Exclusion criteria

Patients with malignancy  
Patients with a fracture after trauma  
Patients with high complex deformity  
Pregnant women

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-07-2023
Enrollment:	210
Type:	Actual

## Ethics review

Approved WMO	
Date:	23-06-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO  
Date: 25-09-2023  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 08-03-2024  
Application type: Amendment  
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	NL83858.058.23