

# Spinal epidural lipomatosis after bariatric surgery

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Primary objective: To evaluate changes in the volume of spinal epidural lipomatosis in the lumbar spine before and after bariatric surgery in patients with obesity.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Spinal cord and nerve root disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON49572

### Source

ToetsingOnline

### Brief title

SEL after bariatric surgery

## Condition

- Spinal cord and nerve root disorders

### Synonym

Fat bulking in the lower spine

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Orthopedie

**Source(s) of monetary or material Support:** Rijnstate vriendenfonds.

## Intervention

**Keyword:** Bariatric surgery, Obesity, Spinal epidural lipomatosis

## Outcome measures

### Primary outcome

The pre- and postoperative volume (mm<sup>3</sup>) of epidural lipomatosis as established from MRI images.

### Secondary outcome

The other study parameters will consist of patient demographics: sex, age, BMI, weight, height and comorbidities, collected from the electronic patient files /records.

## Study description

### Background summary

Spinal epidural lipomatosis (SEL) is a pathological overgrowth of normal adipose tissue in the extradural space within the spinal canal causing compression of the nerve roots and the spinal cord. This can occur idiopathically or secondarily due to obesity, Cushing syndrome, endocrine disorders and it is associated with a high visceral fat accumulation in patients. These patients may present progressive and long standing complaints of back pain, radiating leg pain, neurogenic claudication, decreased pinprick sensation and, in some rare cases, lower extremity weakness. The first description of SEL was given by Lee et al. (4) in 1975. The gold standard for diagnosing SEL is a T1-weighted MRI. In the spine, the lumbar level is the single most frequently affected region by SEL.

About one third of the world population is overweight and it is estimated that by 2030 nearly 40% of the world's adult population will be overweight (Body Mass Index 25-30) and 20% will be considered obese. When the Body Mass Index (BMI) is  $\geq 30$ , adults are classified as obese. Indications for bariatric surgery vary across regions and practices, but a BMI  $\geq 40$  without comorbidities or a BMI  $\geq 35$  with at least one obesity related comorbidity (e.g. hypertension, diabetes, nonalcoholic fatty liver disease, osteoarthritis, or heart disease) classifies a patient as morbidly obese. These levels of BMI are generally accepted indications for bariatric surgery after conservative weight loss measures have failed.

Of all the risk factors for SEL, obesity is a commonly observed comorbidity. For SEL patients these symptoms can result in a severely reduced quality of

life comparable to a classical osteoligamentous spinal stenosis. Treatment of SEL ranges from conservative management to surgical excision. Patients with neurologic deficits caused by compression of SEL, frequently undergo a decompressive procedure by means of laminectomies and fat debulking. For patients without neurologic deficits, weight reduction as part of conservative management is a serious and established option.

To the best of our knowledge, no studies have conducted direct volumetric evaluations and comparisons of SEL in patients before and after bariatric surgery and people with normal weight. One case report described complete remission of SEL in the lumbar region and also remission in back pain symptoms after sleeve gastropasty. In this case report a 48-year-old man is described with obesity and a history of chronic back pain who developed idiopathic spinal epidural lipomatosis (as diagnosed by magnetic resonance imaging) and which subsequently resolved completely after sleeve gastropasty over a 6-month follow-up period. This report suggests that spontaneous accumulation of fat in the epidural space is a dynamic process and sometimes associated with an increase in the peripheral fat mass. It would also be worthwhile to follow bariatric surgery patients for longer postoperatively since it is known that patients can gain weight again after post-sleeve gastropasty. A study with a larger sample, which evaluates the volume of SEL in bariatric patients, before and after surgery, is needed to understand this process even better.

Lumbar spinal stenosis (LSS) is the most common indication for spinal surgery in people older than 65 years. Different studies suggest an estimated prevalence of lumbar spinal stenosis of 11% in the general population and in the clinical population 25 to 39%. Diagnosing and treating lumbar spinal stenosis has an increasing economic impact, the mean cost per patient is  $\$1,010 \pm \$1,13$  (range:  $\$716 \pm \$980$  to  $\$1,442 \pm \$1,170$ ). Apart from the costs, the symptoms in these patients have a substantial impact on mobility, functional autonomy and performance in daily life. SEL is described in about 6% of the patients with symptomatic spinal stenosis. Patients with SEL exhibited more severe pain and less walking ability than those with LSS in the absence of SEL. The results of spinal surgery in patients with SEL are less efficient in comparison to the patients without SEL. Thus, the spinal surgeon may be reluctant to perform spinal surgery in these patients.

This study may help to elucidate whether bariatric surgery can reduce not only the total body weight, but also the volume of SEL in the lower spine and positively influence the different pain symptoms in the patient's back and lower limbs.

## **Study objective**

Primary objective: To evaluate changes in the volume of spinal epidural lipomatosis in the lumbar spine before and after bariatric surgery in patients

with obesity.

## Study design

This is a pragmatic, explorative observational study during which a small convenience sample of patients, that have already undergone a pre-operative MRI (patients with obesity and patients with normal weight) and received bariatric surgery (patients with obesity) in our hospital, will be included. The bariatric surgery patient group will be invited to undergo one postoperative MRI scan, and their changes in the volume of epidural lipomatosis before and after bariatric surgery will be analyzed. The patients with normal weight will be used as a proxy group to which the pre-operative volumes of epidural lipomatosis will be compared to.

## Study burden and risks

During this study participants will undergo one MRI scan. This procedure is safe and poses no (radiation) risks to the participant.

## Contacts

### Public

Selecteer

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### Scientific

Selecteer

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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 from Rijnstate i) who have undergone bariatric surgery and ii) who have had Magnetic Resonance Imaging of the lumbar spine in the 12 months prior to their surgery and iii) who are willing to undergo one repeat MRI for the purpose of this study.

### Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: i) patients who do not want to participate in this study and ii) who do not comply to the inclusion criteria mentioned above.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 23-01-2021

Enrollment: 25

Type: Actual

## Ethics review

Approved WMO

Date: 28-09-2020

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL74712.091.20