

# Transforaminal epidural corticosteroids versus shortacting anesthetic in patients with sciatica: a randomized prospective trial

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The goal is to find answer to the question: do epidural injections with corticosteroids in patients with sciatica have a positive effect on pain, absenteeism from work and number of operations compared to standard care (pain medication only).

<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>	Interventional

## Summary

### ID

NL-OMON41491

### Source

ToetsingOnline

### Brief title

Epidural corticosteroids in the treatment of sciatica

### Condition

- Spinal cord and nerve root disorders

### Synonym

radicular syndrome of lower limbs, sciatica

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Sint Lucas Andreas Ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## **Intervention**

**Keyword:** cost effectiveness, pain management, sciatica, steroid injections

## **Outcome measures**

### **Primary outcome**

Primary outcome measures:

1. Roland Disability Questionnaire
2. Visual Analogue Scale (VAS) for back pain
3. Visual Analogue Scale (VAS) for leg pain
4. Global Perceived effect

### **Secondary outcome**

Secondary outcome measures:

1. satisfaction
2. use of medication
3. absenteeism from work (yes- no)

#### 4. number of operations

## Study description

### Background summary

Sciatica is characterized by radiating pain in an area of the leg typically served by one nerve root in the lumbar or sacral spine/. The most common cause of sciatica is a herniated disk. The estimated annual incidence of sciatica in The Netherlands is 9 cases per 1000 adults (95%BI 8,4-10,2).

The natural history of sciatica is favorable, with resolution of leg pain within 2-3 months from onset in the majority of patients. The international consensus has been that surgery should be offered only if symptoms persist after a period of conservative treatment. Exceptions are patients with severe pain refractory to medication or patients with neurological deficits (cauda equine syndrome, weakness MRC gr 3 or more). These patients are operated regardless of the duration of symptoms.

There are several non-surgical treatment options in patients with sciatica including pain medication, physiotherapy or epidural injections with corticosteroids. The latter is performed by an anesthesiologist under radiological guidance. In the national Dutch treatment guideline for sciatica (2008) the injections are recommended if pain medication fails.

What is meant by \*failing\*? It's not always clear when to refer patients for an injection. Many Hospitals in The Netherlands have their own Pain Department where injections are carried out easily, without different forms of pain medication having been tried. This asks for new research: what is the role of epidural injections with steroids within the treatment protocol for sciatica?

### Study objective

The goal is to find answer to the question: do epidural injections with corticosteroids in patients with sciatica have a positive effect on pain, absenteeism from work and number of operations compared to standard care (pain medication only).

### Study design

a partly blinded\*, randomized, controlled trial.

There are 3 groups:

1) pain medication only

2) pain medication + epidural injection with corticosteroids and local anesthetic

3) pain medication + epidural injection with local anesthetic

\* partly blinded refers to: patients and investigators of course know when they are injected. The injected substance is unknown however.

## **Intervention**

Intervention group 1:

transforaminal epidural injection with 60 mg Depomedrol and 1,5 ml Levobupivacaine. The injection is given under radiological guidance with administration of contrast agent.

Intervention group 2:

transforaminal epidural injection with 1,5 ml Levobupivacaine only. The injection is given under radiological guidance with administration of contrast agent.

## **Study burden and risks**

For all 3 groups:

4 visits to hospital (20 mins max.) During each visit questionnaires are filled in.

For the injected groups there minor risks related to the injections: temporary headache, infection (rare). The risks of radiological procedures and contrast fluid are negligible.

## **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

18- 65 years old;sciatica; 8 weeks;radiologically confirmed discus;correlation between symptoms and MRI abnormalities;VAS 40 or more despite NSAIDs, PCM, of opioids

### Exclusion criteria

paresis MRC gr 3 or more, caudasynndrome;spinal surgery at the same level within 1 year ;lumbar stenosis, spondylolistesis;pregnancy;severe co morbidity (for example cancer)

## Study design

### Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2016
Enrollment:	260
Type:	Actual

## Medical products/devices used

Product type:	Medicine
Brand name:	Chirocaine
Generic name:	Levobupivacaine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Depomedrole
Generic name:	methylprednisolon acetate
Registration:	Yes - NL intended use

## Ethics review

Approved WMO	
Date:	20-08-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	08-04-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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
EudraCT	EUCTR2014-003096-37-NL
CCMO	NL45805.100.15