Transforaminal Epidural Injection in Acute Sciatica

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1. To study effectivity of the epidural injection with analgesic and anti-inflammatory medication to relieve the symptoms within two weeks follow up.It will be evaluated in what percentage of patients the decrease in leg pain is satisfactory in both...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON55906

Source
ToetsingOnline

Brief title
TEIAS

Condition

- Spinal cord and nerve root disorders

Synonym
lumbar radiculopathy, Sciatica

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ynske Meyes Fonds

Intervention

Keyword: Epidural Injection, Sciatica

Outcome measures

Primary outcome

The pain intensity in the leg and the back will be measured with a 10 point horizontal Numeric Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain). The percentage of patients that demonstrated a decrease in NRS legpain < 4 points at two weeks after injection is compared to the percentage of patients that demonstrated this decrease in the prolonged conservative care group, 2 weeks after randomization. This will be calculated again at 4 weeks after randomization.

Secondary outcome

NRS back pain: The pain intensity in the leg and the back will be measured with a 10 point horizontal Numeric Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain). The NRS scores will be measured at baseline and at 1, 2, 4, 10 and 21 weeks after randomization. Oswestry Disability Index (ODI): The functionality of the patient with a focus on walking and daily activities will be measured with the Oswestry Disability Index that is usually measured in sciatica complaints. The scale ranges from 0 (no disability) to 50 (worst disability possible). The ODI scores will be measured at baseline and at 1, 2, 4, 10 and 21 weeks after randomization. EuroQoL (EQ-5D): The EuroQoL (five point EQ-5D) will be used for the cost utility analysis. The EuroQol scores will be measured at baseline and at 2, 10 and 21 weeks after randomization. Likert perceived recovery patient: To measure the perceived recovery a

seven-point Likert scale will be used. The score on this scale vary from *completely recovered* to *worse than ever*. The Likert scores will be measured at baseline and at 1, 2, 4, 10 and 21 weeks after randomization. Costs (Cost intervention, health care use, and loss of productivity): Cost diaries will be filled out at 10 and 21 weeks after randomisation. Complications: PostTEI exacerbation of VAS legpain (>1 point additional leg pain) that lasts for at least 24 hours will be documented as a clinically relevant complication of TEI. Radiological parameters: MRI data will be evaluated by two independent researchers, blinded for clinical and histological data Histology: disc material from the operation will be histologically evaluated and data will be quantified by two independent researchers, blinded for clinical and MRI data Demographic data: demographic data will be collected at baseline TEI data: data with respect to timing of injection, number of injections, legpain after injectie and complications will be documented.

Study description

Background summary

Sciatica is a condition of radicular pain in the leg and is usually caused by herniation of a lumbar intervertebral disc. The herniated disc compresses a lumbar nerve root that continues its route into the sciatic nerve. About 13% to 40% of all people will suffer from sciatica at least once during their lifetime. Sciatica can have severe socio-economic effects; patients are immobilised by the pain they experience and therefore cannot go to work or participate in social events.
Most cases resolve spontaneously with conservative therapy using only standard analgesics and/or physiotherapy. In a large RCT it was demonstrated that outcome of conservative and surgical therapy was comparable after 26 weeks. With this knowledge the guidelines for surgical treatment of sciatica were adjusted and it is nowadays usual care to offer surgery only after at least 8

weeks of conservative care and preferably after 14-16 weeks of conservative care. This decision is made together with the patient in a process of Shared Decision making.
Although this treatment regimen has been demonstrated to be efficacious and cost effective, the burden for a patient during these weeks of conservative care is usually high. We seek to find a type of conservative care to reduce the discomfort due to the pain and to enable the patient to remain physically active. Not only will this add to the quality of life of the patient, but it will also prevent the patient from taking a sick-leave.

Study objective

1. To study effectivity of the epidural injection with analgesic and anti-inflammatory medication to relieve the symptoms within two weeks follow up. It will be evaluated in what percentage of patients the decrease in leg pain is satisfactory in both treatment arms at two weeks follow up. A satisfactory effect is defined as a decrease in NRS (Numeric Rating Scale) leg pain to a value below 4 points on a 10 points scale. It will be evaluated how long the effect lasts. The legpain and functionality at 4 weeks after injection/randomization will also be evaluated to get informed on the responsiveness on TEI in a somewhat later stage.
2. To evaluate the outcome of TEI in the first two weeks after injection as a predictor of NRS legpain at 14-16 and ca 26 weeks after onset of legpain. The hypothesis is that being non-responsive to TEI within two weeks, predicts an unsatisfactory condition after 14-16 weeks of suffering. This is the category of patients that in contemporary care in the Netherlands will be offered a surgical intervention. If our hypothesis is correct, in the future, this population of patients can be offered a surgical intervention at an earlier timepoint.
3. To evaluate the cost-effectivity of analgesic/anti-inflammatory epidural injections to relieve symptoms of early sciatica
4. A portion of the patients in this study will eventually have an MRI of the lumbar spine and/or will eventually be operated. MRI data and histological data from disc material will be correlated to clinical data.

Study design

This is a randomized controlled trial on patients suffering from acute sciatica (3-8 weeks pain in the leg with a NRS >= 6) (see inclusion and exclusion criteria) in which consecutive patients who meet the inclusion criteria are invited to participate in the trial. Clinical and demographic data are gathered, as well as details on the injection (timing and frequency) and prevailing complications.
NRS legpain that decreases below the value of 4 within two weeks after TEI is documented as successful effect of TEI. NRS legpain that remains higher than a value of 4 at a time interval of two weeks after TEI makes a patient eligible

for surgery if the patient requests for surgery. General guidelines for timing of surgery will be conducted, meaning that the patient is encouraged to postpone surgery till 14-16 weeks after onset of pain. This decision is made using Shared Decision Making and it is possible that the patient is operated before the 14-16 week timepoint. The patients who are randomized cannot be operated in the first two weeks after randomization, unless sudden loss of strength or a cauda equina syndrome is reported. Four weeks after injection/randomization the outcome measures are measured again to be informed on the late effect of TEI.
Randomization will take place using block randomization.

Intervention

One treatment arm will be treated with TEI:
- For injections below L3 :1,5ml lidocaine 2% and 40mg depomedrol is injected transforaminally in close proximity of the nerve root, according to usual care
- For injections above L3: 1,5 ml lidocaine 1% and 10mg dexamethasone is injected transforaminally in close proximity of the nerve root, according to usual care
- If necessary, oral pain medication and/or physiotherapy

The other treatment arm will be treated with only oral pain medication and/or physiotherapy.

Study burden and risks

Burden: participants will be asked to fill in questionnaires. This will be performed electronically and the estimated burden is low.
Risk: risks, predominantly from treatment with TEI, are equal to risks occuring from usual care for sciatica. TEI as an intervention tool is considered usual care for sciatica patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Suffering from sciatica Leg pain of 6 or more on a 10 point NRS (Numeric Rating Scale) scale with a duration of >3 and <8 weeks Informed consent

Exclusion criteria

Age under 18 years
Condition preventing to receive TEI
Severe scoliosis
TEI received in 6 months before randomization date
Surgery for sciatica at the same level
Surgery for sciatica at another level within one year before inclusion
Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2019
Enrollment:	142
Type:	Actual

Ethics review

Approved WMO

Date:	25-03-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-06-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-09-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-11-2024
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	NL67570.058.18