Transforaminal Epidural Steroid Injections for Acute Lumbosacral Radicular Syndrome without prior consultation with a neurologist or diagnostic imaging.

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The aim of this study is to evaluate the pain improvement of patients with aLRS treated with TFESI, after straight referral from the GP to the pain specialist without diagnostic imaging and prior consulta-tion with a neurologist. Pain improvement...

Ethical review	Not approved
Status	Will not start
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON55127

Source
ToetsingOnline

Brief title
Fast-track TFESI for LRS

Condition

- Spinal cord and nerve root disorders

Synonym
Acute Lumbosacral Radicular Syndrome, pain in leg

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: lokaal afdelingsbudget

Intervention

Keyword: Acuut Lumbosacral Radicular Syndrome, Pain, Transforaminal Epidural Steroid Injection

Outcome measures

Primary outcome

The primary outcome of this study is pain improvement three weeks after TFESI.

Pain improvement will be assessed using a 5-point Likert scale previously used

to assess decline in pain intensity for patients with acute pain. Patients will

be asked whether they experience: (1) no improvement, (2) minimal improvement,

(3) much improvement, (4) very much improvement or (5) complete pain relief.

Secondary outcome

Secondary outcomes are intensity of pain measured with the Numeric pain Rating

Scale (NRS), severi-ty of pain measured with the Brief Pain Inventory (BPI),

quality of life measured with the Short Form 12 Item Health Survey version 2

(SF12v2), anxiety and depression measured with the Hospital Anxiety and

Depression Scale (HADS), catastrophizing of pain measured with the Pain

Catastrophizing Scale (PCS), effect of treatment measured with a Global

Perceived Effect (GPE) scale, and complications.

Study description

Background summary

With an incidence of 9 per 1000 patients per year in the Netherlands, acute lumbosacral radicular syn-drome (aLRS) is a common problem. The most common cause is a herniated disc. The natural course is generally favourable; the radiculopathy usually diminishes within three months and con-servative treatment suffices. In the first six to eight weeks, conservative treatment is therefore first choice. If oral medication gives insufficient pain relief, generally a transforaminal epidural steroid injection (TFESI) is performed. This treatment is seen as part of conservative therapy. Also, when pain has been present for more than three months, a TFESI is often carried out before considering surgical treatment as it is less invasive. TFESI is part of standard care and is covered by the standard health insurance package.

TFESI consists of administration of a long acting steroid in the epidural space around the nerve root in the neuroforamen. In aLRS due to a herniated disc, an inflammatory process is involved. The injected steroid reduces inflammation thereby limiting oedema and thus reduces pressure to the nerve root. In addition, persistent noxious stimulation from inflammatory mechanisms might explain central sensitization in patients with aLRS. The anti-inflammatory effect of steroids might prevent central sensitization. There is a negative correlation between the duration of aLRS and the responsiveness to epidural steroid injections.

Upon presentation at the general practitioner (GP), patients with aLRS are treated conservatively with oral pain medication for a period of six to eight weeks. In this period, patients are only referred to a neurologist when the following conditions apply: suspected cauda equina syndrome, severe paresis, a (history of) malignancy or if the pain could be explained by another rare and/or serious condition. In addition, a patient is referred to a neurologist if oral pain medication gives insufficient pain relief, at times, already within the first six to eight week period. Generally, the neurologist, guideline conform not the GP directly, refers these patients to a pain specialist for TFESI. Generally these patients are offered a TFESI as part of conservative treatment. Generally, the neurologist, guideline conform not the GP, refers these patients to a pain specialist for TFESI. Within Noordwest Ziekenhuisgroep it is estimated that neurologists refer the majority of these patients with pain despite medication to the pain specialist for a TFESI.

Prior to referring a patient to a pain specialist, diagnostic Magnetic Resonance Imaging (MRI) is often requested by the neurologist. However, in accordance with the current guideline, imaging for aLRS is only indicated when surgical intervention is considered or symptoms may be explained by another serious condition.1 There is consensus with the Dutch Association for Neurology (NVN), the Dutch Association for Neurosurgery (NVVN) and the Dutch Orthopaedic Association (NOV) that diagnostic imaging is performed only in case of suspicion of a serious condition causing the radicular pain or if surgical treatment is considered, as also expressed in 'Wise choices for a low back hernia' by the Order of Medical Specialists, ZonMw and Dutch Patient Federation

(NPCF).15

Preceding a TFESI, patients always have an intake at the pain clinic to confirm the diagnosis aLRS and to determine the nerve root to be treated. Diagnostic imaging is not required for TFESI. Consulta-tion with a neurologist and diagnostic imaging might be superfluous prior to a TFESI for aLRS; this suggests cost-effective changes in logistics could be made. In addition, this change in logistics could improve responsiveness to TFESI given the negative correlation between the duration of aLRS and the responsiveness to TFESI. During this feasibility study only patients with aLRS and unbearable pain despite oral pain medication who otherwise would also most likely receive a TFESI will be includ-ed, but without prior consultation with a neurologist and diagnostic imaging.

Study objective

The aim of this study is to evaluate the pain improvement of patients with aLRS treated with TFESI, after straight referral from the GP to the pain specialist without diagnostic imaging and prior consulta-tion with a neurologist. Pain improvement will be assessed three weeks after treatment using a 5-point Likert scale.

Study design

This single centre feasibility study will be conducted in the Noordwest Ziekenhuisgroep location Alkmaar in collaboration with GPs and will assess the efficacy of a change in logistics of a clinical pathway for patients treated for aLRS. This feasibility study will be used for sample size calculation for a Randomized Clinical Trial. A follow-up study can evaluate safety and cost-effectiveness, comparing usual care to the change in logistics implemented for this study. This study will take a year to complete.

Treating patients suffering from unbearable pain despite oral medication with TFESI is part of usual care and is covered by the standard health insurance package.

Intervention

Treating acute LRS with a TFESI, by straight referral from the GP to the pain physician without prior consultation with a neurologist or diagnostic imaging. The pain physician does an intake to confirm the diagnosis LRS and to determine which nerve root to treat.

Study burden and risks

The change in logistics implemented for this study may potentially lead to a

small group of patients receiving a TFESI which they would not have received outside study setting resulting in overtreatment. However, pain reduction due to natural course within referral interval is always a possibility. Furthermore, only patients with unbearable pain despite medication are included in this study. In principle, these patients are all eligible for a TFESI. Due to the adapted logistics in the study protocol, the patient sees the anesthetist-pain specialist earlier. The logistics implemented during this study could lead to patients a shorter period of pain complaints for the patient. There is also an unethical aspect of prolonged unbearable pain. During this study there is even a chance that patients who would otherwise be immediately referred to a neurosurgeon will be adequately treated earlier.

TFESI is part of conservative treatment and usual care. Omitting diagnostic imaging might lead to aforementioned red flags possibly being missed, however momentarily neurologists also do not al-ways perform diagnostic imaging either. If anamnesis shows there is a chance of underlying suffering (exclusion criteria), patients are referred to a neurologist, conform the guideline.

Patients will get an intake appointment and an appointment for TFESI (invasive treatment). Patients are asked to fill in a questionnaire, before (baseline) and three weeks after treatment. Patients will be expected to be treated much earlier than with usual care which might lead to a shorter duration of inadequate pain relief.

If successful, patients treated with a TFESI will benefit from pain relief. This may lead to reduction of pain medication, among others opiates. Furthermore, if patients benefit from pain relief they will more likely be able to return to work, reducing sick leave. The change in logistics implemented for this study could improve responsiveness to a TFESI as there is a negative correlation between the dura-tion of aLRS and the responsiveness to a TFESI.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Male/female, 20 to 50 years
- Patients with a first time presentation of aLRS in the involved dermatome
- Pain radiating in the leg, following spinal segments L4, L5 or S1
- Predominantly leg pain
- Pain score of NRS *6
- The symptoms are present for less than six months
- There is no indication for immediate referral to a neurologist or neurosurgeon, according to the Dutch lumbosacral radicular syndrome guideline.
- Subject is able and willing to provide informed consent
- Subject is able and willing to comply with the protocol and follow-up schedule

The current guideline from the Dutch Spine Society provides extensive screening methods to diag-nose aLRS. For instance, prominent leg pain, typical dermatomeric pain and increase in radiating pain at pressure-increasing moments have shown to be strong predictors of nerve root compression.1 If anamnesis shows there is a chance of underlying suffering (exclusion criteria), patients are referred to a neurologist, conform the guideline.

Exclusion criteria

- History of back surgery
- History of LRS with radiation that follows the same side and segmental pattern
- Pain present since recent trauma
- Unexplained weight loss
- Severe back pain with fever
- Predominantly back pain during the night

- Previous Borrelia Burgdorferi infection
- Patient has a (history of) malignancy
- Bilateral limb pain
- Predominantly back pain of *50%
- Pain score of NRS <6
- Cauda equina syndrome or acute severe paresis or progressive paresis (within a few days)
- History of coagulation disorders
- Pregnancy or breastfeeding
- Immunocompromised
- Previous adverse reactions to contrast agents, methylprednisolone or lidocaine.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	04-04-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL70254.018.21