ISRCTN12574253 https://doi.org/10.1186/ISRCTN12574253

Epidural Sacral Injection study: effect of volume and triamcinolone on chronic lumbosacral radiculopathy?

Submission date
02/04/2005

Recruitment status
No longer recruiting

Registration date
18/05/2005

Overall study status
Completed

Last Edited
16/12/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2137

Study information

Scientific Title
Epidural Sacral Injection study: effect of volume and triamcinolone on chronic lumbosacral radiculopathy?

Acronym
ESI

Study objectives
ESI (Epidural Sacral Injection) is a method of treating low back pain and radiculopathy that is the subject of considerable discussion. Although the method has been in existence for nearly 100 years, there are only a few good randomised controlled studies. In Nelemans et al (2000), evidence for the method is given as weak, and studies of a high scientific quality are sought. To investigate these factors in greater detail, randomised controlled studies are needed to clarify the effect of volume and steroids versus placebo.

Many patients with chronic low back pain and sciatica feel that they have few good therapeutic options besides surgery. Only a few patients with sciatica are suitable for surgical treatment. The surgeon needs a correspondence between the clinical level of radiculopathy and Magnetic Resonance (MR) diagnosis of disc protrusion. Many patients lack this correspondence. We therefore want to conduct the study on patients with clinical signs of lumbosacral radiculopathy, where the pain has lasted for more than 12 weeks (chronic) and where surgical treatment is not indicated at the time of inclusion due either to lack of correspondence between clinical and MR finding or low Oswestry Disability Index (ODI).

In our study, we wish to use a corticosteroid preparation with a weak anti-inflammatory effect. Triamcinolone acetonide in a strength of 40 mg/ml and a quantity of 1 ml meets this requirement. The effect is to be compared with placebo (2 ml NaCl 0.9% subcutaneously) and volume (30 ml NaCL 0.9% epidural). In many studies, injections have been used with a small volume (less than 10 ml). We will use a volume of 30 ml to be sure that the medicinal product is distributed throughout the epidural space in the lumbosacral column up to level L2. If our study can demonstrate a significant therapeutic effect for ESI of steroid, the method could become an important tool in the treatment of patients with low back pain and radiculopathy. We could also clarify in the study whether there are special subgroups of patients with radiculopathy (Signal changes in the disc, Covered prolapse, Free prolapse, Thickened nerve root, Disclosed nerve root) that respond better to steroid injection.

If the method can also be proven to be easy to perform, and associated with few serious complications and adverse drug reactions, it could become useful in both the treatment and rehabilitation of sciatica patients. At present, we do not know enough about the risk associated with use of the method, the incidence of side-effects and what should be regarded as adequate follow-up of patients. Hopefully, a study could yield valuable information on this. Given a good effect from the treatment and a low incidence of side-effects, we will probably be able to substantiate a positive gain in the form of reduced suffering for the individual in addition to a socioeconomic gain from patients recovering their health and being able to return to work more quickly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Committee for Medical Research Ethics in Norway (P REK NORD), 09/01/2004, ref: 105 /2003

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Lumbosacral radiculopathy
Sciatica

Interventions
Epidural sacral injection with triamcinolone versus saline

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Triamcinolone

Primary outcome measure
Oswestry Disability Index (ODI)

Secondary outcome measures
1. European Quality of life measure (EQ5-D)
2. Fear-Avoidance Beliefs (FABQ)
3. Visual Analog Scale (VAS) back pain, leg pain, general health
4. Number of patients referred to all types of Back Surgery during follow-up

Overall study start date
01/05/2005

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Age: 20-60 years
Sex: Both
Symptoms: Sciatic pain >12 weeks
Objective: Radiculopathy L3-S1

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
124

Key exclusion criteria
1. Indication of acute back surgery at the time of inclusion
2. Previous back surgery
3. Previous epidural or nerve root injection for low back pain or sciatica
4. Red flags
5. Yellow flags
6. The patient must not have noticed an improvement in symptoms or certralisation of pain from leg to back for the previous two weeks before inclusion
7. Pregnancy
8. Anticlotting therapy with Warfarin
9. Ongoing treatment with Non-Steroidal Anti-Inflammatory Drug (NSAID)
10. Magnetic Resonance Imaging (MRI) findings showing lateral recess stenosis of osteogenic aetiology, tumor, bleeding, dural fistula, synovial cyst, dysraphia conditions

Date of first enrolment
01/05/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Norway

Study participating centre
Gullveien 3
Terraak
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7980

Sponsor information

Organisation
University Hospital of North Norway - Neurosurgery department

Sponsor details
-
Tromsoe
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Sponsor type
University/education

ROR
https://ror.org/030v5kp38

Funder(s)

Funder type
University/education

Funder Name
Health North RHF (Norway)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/09/2011		Yes	No
Results article	results	07/02/2015		Yes	No