The use of direct nerve visualisation with the Evotouch/7starscope compared to the conventional fluoroscopy technique for transforaminal epidural injection.

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

Summary

ID

NL-OMON51663

Source
ToetsingOnline

Brief title
Ster study

Condition

- Spinal cord and nerve root disorders

Synonym
nerve pain, Radicular pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: 7starscope, Epidural steroid injection, Fluoroscopy

Outcome measures

Primary outcome

Correct needle placement (Yes/No) as confirmed with fluoroscopy

Secondary outcome

1. Inadvertent intravascular positioning (Yes/No)

2. Brief pain inventory at baseline and 2, 4, 8 and 12 weeks after TFEI

3. Global perceived effect at baseline and 2, 4, 8 and 12 weeks after TFEI

4. Number of repositioning procedures required for adequate contrast spread

around the nerve root.

5. Procedure difficulty scoring scored by the pain specialist directly after

the TFEI procedure.

Study description

Background summary

In this exploratory study we will investigate the use of the Evotouch/7starscope device to perform transforaminal epidural injections (TFEI) in patients with pain due to lumbar radiculopathy. The advantage of this device is that optimal needle positioning can be obtained by direct visualisation of neurovascular structures without the need of fluoroscopy (standard of practice). Fluoroscopy has several disadvantages including radiation exposure to patient and medical staff, high cost equipment and the need for specialized facilities which makes its use impossible in out-patient clinics or at the bedside.With this study we can investigate whether fluoroscopy is not needed in the future to perform a TFEI procedure.

Study objective

We hypothesize that using the Evotouch/7stascope, ultrasound guided TFEI procedures are non-inferior to the golden standard with fluoroscopy, which means correct placement of the needle within the neuroforamen without intravascular positioning.

Study design

The study will have an exploratory, non-inferiority design.

Intervention

We will study two groups. In the first group patient will be treated using the standard technique of fluoroscopy, in the intervention group patients will be treated using the Evotouch/7starscope. The main objective of the study is to compare the two methods. For both techniques fluoroscopy will be used to confirm definite needle positioning.

Study burden and risks

The risks of the study are low. There are risks associated with the epidural injection such as infection, bleeding, soar skin at puncture place, no treatment effect en temporary motor loss of the leg due to the local anesthetic. De different intervention groups do not alter this risk. In every group definite needle positioning will be checked using fluoroscopy which is the golden standard. The questionnaire do not form a risk for the patient.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2 Albinusdreef 2
Leiden 2300 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2 Albinusdreef 2
Leiden 2300 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age 18 years or higher
2. Unilateral, single level radicular pain at level L2-L3, L3-L4, L4-L5 or L5-S1
3. Pain score of 4 or higher on a scale from 0-10

Exclusion criteria

1. The presence of coagulation disorders or the use of anticoagulants that interfere with the procedure and cannot be stopped during the procedure
2. Presence of an infection at the lumbar spine
3. History of a spinal tumor
4. Previous surgery with fixation of the lumbar spine
5. Serious spinal deformity inducing large anatomic alterations
6. Allergic reaction to contrast dye or local anaesthetics used during the procedure
7. Inability to provide informed consent
8. Pregnancy

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2023
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Evotouch 7starscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-12-2022
Application type:	First submission
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	NL82510.058.22