

Ultrasound guided versus nerve stimulation guided distal sciatic nerve block

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Ethical review	Approved WMO
Status	Pending
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON29935

Source

ToetsingOnline

Brief title

Ultrasound versus nerve stimulation nerve block

Condition

- Procedural related injuries and complications NEC
- Nervous system, skull and spine therapeutic procedures

Synonym

peripheral nerve block

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: nerve stimulation, regional anesthesia, ultrasonography

Outcome measures

Primary outcome

The amount of injected local anesthetic

Successrate

Block characteristics (onset time and duration)

Secondary outcome

Block procedure time

Attempts to localize the nerve

Blockprocedure related pain

Patient satisfaction

Neurologic complications

Study description

Background summary

Ultrasound guidance for peripheral nerve blocks have been described for brachial plexus and femoral nerve blocks. The reports showed that ultrasound guidance improved the successrate and onset time and reduced the amount of local anesthetic and had few complications compared with the nerve stimulation guided techniques. Recently it is described that ultrasound assisted sciatic nerve localization is potentially valuable for sciatic nerve blocks.

Study objective

We hypothesize that ultrasound visualization of the distal sciatic nerve with subsequent ultrasound guided injection of a reduced amount of local anesthetic will result in shorter performance times, equivalent block quality (sensory and motor onset time and duration) and less patient discomfort compared with the

present technique. (nerve stimulation guided distal sciatic nerve block)

Study design

A prospective randomized single blinded interventional study.

Intervention

In the ultrasound guided distal sciatic nerve blocks, the sciatic nerve will be visualised, hereafter under direct ultrasound guidance the needle will be introduced. Needle position will be confirmed by electrical nerve stimulation. Under ultrasonographic control local anesthetic is injected. If no circumferential spread occurs around the nerve, the needle will be repositioned in order to obtain this pattern of spread of local anesthetic. In the nerve stimulation group, the needle insertion point is determined based on anatomical reference points. By electrical nerve stimulation the exact needle position is determined and hereafter local anesthetic is blindly injected.

Study burden and risks

The risks the patient faces when participating in this research project are not different compared to the normal clinical situation when a distal sciatic nerve block is performed for surgical anesthesia of the lower leg or foot. In daily clinical practice the following incidents are routinely tried to avoid: intoxication with local anesthetic due to resorption or intravascular injection and intraneural injection with subsequent mostly temporary nerve damage.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients, (ASA 1 to 3) undergoing surgery of the lower limb or foot under locoregional anesthesia with a distal sciatic nerve block.

Exclusion criteria

hepatic and or renal disease, pregnancy, allergy for local anesthetics, inability to communicate adequately

Study design

Design

Study type: Interventional

Masking: Single blinded (masking used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2006

Enrollment: 40
Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL12334.091.06