Comparison of percutaneous electrical nerve stimulation and ultrasound imaging for nerve localization.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20483

Source
Nationaal Trial Register

Brief title
Nerve stimulation-ultrasound

Health condition

Healthy subjects

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Anesthesiology
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

Distance between point of minimal electrical nerve stimulation and point where the nerve is most superficial visualized by ultrasound.

Secondary outcome

Distance between each stimulation point and the stimulated nerve.

Study description

Background summary

Rationale:
Transcutaneous electrical nerve stimulation via a Stimuplex® pen is used to localize superficial nerves noninvasively before the performance of a peripheral nerve block. In recent years high-resolution ultrasonography has been used increasingly to visualize peripheral nerves for peripheral nerve blocks. Thus, the aim of this study is to correlate the place of the best transcutaneous electrical nerve stimulation with the subcutaneous depth of these nerves of the axillary and interscalene brachial plexus. Further and more importantly, the ultrasound picture will delineate sensitive structures that are at risk, if the puncture site is localized by the transcutaneous nerve stimulation.

Objective:
The aim of this preclinical study in volunteers is to compare the results of percutaneous electrical nerve stimulation for nerve localization with the results of high-resolution ultrasonograpy. Thus, the value of percutaneous nerve stimulation to predict nerve location will be assessed by high-resolution ultrasound. Furthermore ultrasonography will reveal how often the puncture sites revealed by transcutaneous stimulation will put sensitive structures at risk during peripheral nerve blockade.
Study design: single centre, prospective, study in volunteers done by two blinded observers
Study population: volunteers, age older than 18 years, American Society of Anesthesiologists (ASA) classification I to II.

Intervention:
In volunteers, the interscalene and axillary plexus will be investigated with a percutaneous nerve stimulator. One investigator identifies the points of the skin where nerves are most easily stimulated (lowest current). Thereafter, another investigator unaware of the results of the nerve stimulation will visualize the plexus and identify the nerves.

Main study parameters/endpoints:
Primary endpoint: Do the points of the skin with lowest possible percutaneous electrical stimulation correlate with the points where the nerves are most superficial to the skin? Thus, are the points actually identical or how far are they away from each other? Furthermore, how often is there a sensitive structure between the puncture site as given by transcutaneous nerve stimulation and the nerve as seen in ultrasonography?

Secondary endpoints: Does the lowest current that can actually evoke a motor response correlate with the distance of the nerve from the skin?

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Percutaneous nerve stimulation with the resultant motor response is mostly non-painful, but may be experienced as uncomfortable. Anyway, slightly painful stimulation may occur, but will be avoidable in most cases. Furthermore, all volunteers may abstain from any further stimulation at any time. Neither percutaneous nerve stimulation nor ultrasound – as used here – has any risk to induce temporary or permanent tissue damage. The only thinkable serious risk is an allergic reaction to Tegaderm foil or ultrasound gel. Anyway, only mild, localized reactions to these materials have been described.

Study objective

1. The point of the skin with best possible transcutaneous nerve stimulation correlates with the point of the skin most superficial to the nerves stimulated within a range of 3 mm;

2. Ultrasound will reveal a significant number of sensitive structures (mainly vessels), that are at risk when using a pure nerve stimulator-guided technique;

3. The distance between the skin of best possible nerve stimulation and the stimulated nerve will be correlated (r ¡Ý 0.8) with the distance between nerve and skin, as observed by ultrasound.

Study design

N/A

Intervention

Percutaneous electrical nerve stimulation and ultrasound scanning after sticking a perforated foil to the interscalene and supraclaviculair region.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy volunteers;

2. Aged older than 18 years;

3. Informed consent.

Exclusion criteria

1. No written informed consent;

2. Infection at the site of investigation;

3. Known allergy to adhesive foil or ultrasound gel;

4. Implanted pacemaker or cardiodefibrillator (ICD);

5. Neurologic deficit of the arm;

6. Known peripheral neuropathy;

7. Pregnancy or lactation period;

8. Aged 18 years or younger.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-12-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-02-2010
Application type:	First submission

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
NTR-new	NL2089
NTR-old	NTR2206
Other	MEC : 09/017
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A