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

Gepubliceerd: 09-02-2010 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20483

Bron
Nationaal Trial Register

Verkorte titel
Nerve stimulation-ultrasound

Aandoening

Healthy subjects

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Anesthesiology
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy volunteers;

2. Aged older than 18 years;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-12-2009
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2089
NTR-old	NTR2206
Ander register	MEC : 09/017
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A