Optical Tissue Stylet: Descriptive observational study into paravertebral space detection in humans.

Gepubliceerd: 13-01-2012 Laatst bijgewerkt: 19-03-2025

The primary objective of the trial is to investigate if the optical tissue stylet technology can reliably identify the thoracic paravertebral space. Diffuse reflectance spectra will be acquired during needle advancement, with custom-made needle...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23308

Bron
NTR

Verkorte titel
OTS PS

Aandoening

regional anesthesia
needle placement
paravertebral space

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Department of Anesthesiology
P.O. Box 9101
6500 HB Nijmegen
+31 (0)24 3611111
Overige ondersteuning: Philips Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

This is an observational study. No outcome is measured.

Toelichting onderzoek

Achtergrond van het onderzoek

The primary objective of the trial is to investigate if the optical tissue stylet technology can reliably identify the thoracic paravertebral space. Diffuse reflectance spectra will be acquired during needle advancement, with custom-made needle stylets that contain optical fibers. The study takes place at the Radboud University Medical Centre in Nijmegen, The Netherlands. All patients are recruited in the Netherlands.

Doel van het onderzoek

The primary objective of the trial is to investigate if the optical tissue stylet technology can reliably identify the thoracic paravertebral space. Diffuse reflectance spectra will be acquired during needle advancement, with custom-made needle stylets that contain optical fibers.

Onderzoeksopzet

Measurements and observations take place during the procedure and subsequent surgery. No follow-up is required for this study.

Onderzoeksproduct en/of interventie

A stylet equipped with optical fibers is used to collect data during routine performance of paravertebral blocks for elective surgery. In addition, methylene blue will be injected to confirm paravertebral needle placement during surgery.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Elective unilateral thoracic surgery;

2. Age between 18 and 80 years of age;

3. Male and female subjects;

4. Ability and willingness to provide informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Photodynamic therapy;

3. Contraindications to regional anesthesia and/or allergy to amide local anesthetics;

4. Subjects < 18 years of age or >80 years of age;

5. Severe coagulopathy;

6. Subjects with severe thoracic deformities;

7. Subjects with contraindications to methylene blue.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-01-2012
Aantal proefpersonen:	12
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-01-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35212
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3098
NTR-old	NTR3238
CCMO	NL37671.091.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35212

Resultaten

Samenvatting resultaten
N/A