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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23308

Source
NTR

Brief title
OTS PS

Health condition

regional anesthesia
needle placement
paravertebral space

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Department of Anesthesiology
P.O. Box 9101
6500 HB Nijmegen
+31 (0)24 3611111
Source(s) of monetary or material Support: Philips Research

Intervention

Outcome measures

Primary outcome

This is an observational study. No outcome is measured.

Secondary outcome

This is an observational study. No outcome is measured.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Stefan Roggeveen

[default]
The Netherlands
Scientific
Stefan Roggeveen
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2012
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	13-01-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35212
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3098

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

Study results

Summary results

N/A