Optical Tissue Stylet - descriptive observational study into paravertebral space detection in humans

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON35212

Source
ToetsingOnline

Brief title
OTS PS

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
correct needle placement

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: middelen door sponsor (industrie);deels personeel uit eigen budget

Intervention

Keyword: needle placement, paravertebral space, regional anesthesia, tissue identification

Outcome measures

Primary outcome

Main study parameters are:

1. Successfully acquired diffuse reflectance spectra obtained in the thoracic paravertebral space, and spectra obtained during needle advancement.

2. Confirmation of sonographic thoracic paravertebral localization, defined as tissue imaging in all locations of the needle where the diffuse reflectance spectra have been collected .

3. Recordings of reaction to a small test dose of lidocaine 2% with epinephrine 1:200.000 at target position for regional anesthesia (to exclude vascular localization of the needle)

4. *certainty score* on a 3-point scale (1 = uncertain, 2 = certain, 3 = very certain) provided by the physician for assignment of the type of tissue present at the needle tip, based on the information available from imaging and/or aspiration and/or reaction to a small injection of epinephrine.

Secondary outcome

Methylene blue will be injected after the administration of local anesthetic. Subsequently, an additional confirmation of correct needle placement within the paravertebral space will be obtained by direct visual observation of the dye in the thoracic paravertebral space by the thoracic surgeon during surgery.

Study description

Background summary

For effective regional anesthesia and interventional pain treatments, correct needle (and catheter) placement is crucial. Currently, needle placement is done under image guidance. However, accuracy of needle placement could still be improved if information would be available that would complement the current imaging and electrical stimulation methods. We have developed a system based on optical spectroscopy that has the potential to provide such complementary information.

This study will be an observational study in a limited number of subjects to investigate if the method can reliably identify the paravertebral space. Detection of the paravertebral space is of particular relevance to the fields of regional anesthesia and interventional pain treatment.

Subjects will be recruited via the preoperative screening clinic. Under general anesthesia a thoracic paravertebral block at 3 levels, consisting of 2 single shot blocks and 1 continuous block, will be performed which is a standard anesthesia procedure for these types of surgery. Both the single injection thoracic paravertebral blocks in each subject will be evaluated in this study. A needle containing an optical stylet will be inserted towards the sonographic endpoint in the paravertebral space; during needle advancement data will be collected with the optical tissue stylet system. The position of the needle tip during advancement and at the endpoint will be confirmed by real-time ultrasound imaging. A testdose of local anesthetic with epinephrine is administered in order to exclude vascular needle placement. Methylene blue will be injected after the administration of local anesthetic. Subsequently, an additional confirmation of correct needle placement within the paravertebral space will be obtained by direct visual observation of the dye in the thoracic paravertebral space by the thoracic surgeron during surgery. After the measurements, the needle and optical stylet will be withdrawn and disposed of. Off-line,data analysis of the optical spectra will be performed, to investigate the potential of the optical tissue stylet technology to reliably discriminate the paravertebral space from other tissues encountered during needle advancement.

In case of positive results additional studies will be set up, for instance to explore the potential of the optical tissue stylet technology to detect epidural acces, and accidental needle insertion into epidural veins. At a later stage, one could envision studies investigating if providing the optical tissue stylet data to the physician during a procedure results in improved procedure success rates. For more information see pages 10, 11 and 12 of the corresponding protocol.

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

This is a non-randomized descriptive observational study.

Study burden and risks

The procedure of inserting the needle and collecting the data will take about 20 minutes. This is about 5 minutes longer than the standard procedure. Subjects will not experience any discomfort as the needle punctures will be performed under general anesthesia, which is common practice in these surgical procedures. Methylene blue is a commonly used dye in patients during medical (diagnostic) procedures. It is used for example in endoscopic polypectomy, chromo-endoscopy and sentinel lymph node dissections. It can also be administered intravenously, to treat methemoglobinaemie, for example as the result of use of prilocaine. Apart from discoloration of urine, side effects are infrequent.
There is no direct benefit for the group of subjects; however, the results of this investigation may in future assist the improvement of regional anesthesia and interventional pain procedures.

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

Elective unilateral thoracic surgery
Age between 18 and 80 years of age
Ability and willingness to provide informed consent

Exclusion criteria

Pregnancy
Photodynamic therapy
Contraindications to regional anesthesia and/or allergy to amide local anesthetics.
Subjects < 18 years of age or >80 years of age
Severe coagulopathy
Subjects with severe thoracic deformities

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2012
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-03-2012
Application type:	Amendment
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

ID: 23308
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37671.091.11
OMON	NL-OMON23308