Optical tissue stylet - observational study into vascular access in humans

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

Summary

ID

NL-OMON35810

Source
ToetsingOnline

Brief title
OTS VA

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
intravascular needle placement

Research involving
Human

Sponsors and support

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

Intervention

Keyword: interventional pain procedure, needle placement, regional anesthesia, tissue identification

Outcome measures

Primary outcome

Main study parameters are:

1. Successfully acquired diffuse reflectance spectra obtained in subcutaneous fat surrounding the veins in the anterior forearm, and spectra obtained with the needle tip inside veins in the anterior forearm.

2. Recordings of positive/negative aspiration results for the locations where the diffuse reflectance spectra have been taken.

3. Confirmation images by ultrasound, at the locations where the diffuse reflectance spectra have been collected.

4. Estimates of the diameters of the punctured veins, based on information from ultrasound imaging.

5. Percentages correctly identified positive and negative vessel punctures, where the identification is provided by an observer who only has access to the diffuse reflectance spectra, and is blinded to all other aspects of the procedures.

Secondary outcome

not applicable

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 volunteers to investigate if the method can reliably discriminate vascular (venous) from non-vascular punctures. Detection of vascular access is of particular relevance to the fields of regional anesthesia and interventional pain.

Volunteers will be recruited via flyers and posters. The study will encompass one visit per subject. Subjects will be randomly divided into two groups. Per group, a different needle endpoint has been defined: for one group the needle endpoint will be in the subcutaneous fat of the anterior forearm, for the other group, the needle endpoint will be inside a vein in the anterior forearm. During the visit, a needle containing an optical stylet will be inserted towards the needle endpoint, where data will be collected with the optical tissue stylet system. The position of the needle tip at the endpoint will be confirmed by ultrasound imaging and aspiration. After the measurements, the needle and optical stylet will be withdrawn and disposed of.
Off-line,prediction of the needle endpoints based on the diffuse reflectance spectra will be done by a blinded observer.

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 access, 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 detailed information, see pages 9 and 10 of the corresponding protocol.

Study objective

The primary objective of the trial is to investigate if the optical tissue stylet technology can reliably discriminate intra-vascular (venous) from non-vascular punctures. Diffuse reflectance spectra will be acquired for these two situations, with custom-made needle stylets that contain optical fibers.

Study design

This is a single-blind randomized observational study

Study burden and risks

The procedure of inserting the needle and collecting the data will take about 5 minutes.
Subjects may experience some discomfort, similar to, or less than the discomfort that subjects can experience during normal blood sample collection.
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. The volunteers will receive a small but reasonable compensation for the potential discomfort.

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

category 1 of the ASA physical status classification system ("healthy")

Exclusion criteria

Subjects who undergo photodynamic therapy, subjects < 18 years of age, pregnant subjects, and subjects who have coagulation deficiencies will be excluded from participation

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-06-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2011
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL36528.091.11