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Optical Tissue Stylet - study into vascular access in humans

Submission date
13/02/2015

Recruitment status
No longer recruiting

Registration date
25/02/2015

Overall study status
Completed

Last Edited
08/03/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sometimes during an injection a blood vessel is accidently punctured. This unintended puncture may lead to serious complications. Spectral Tissue Sensing (STS) is a technique based on light, which can provide information about the tissue that is in front of the tip of the needle. Along with the image provided by ultrasound, this information might help to place the needle in the right position. To confirm this we would like to investigate this by placing a needle in the arm of healthy volunteers, in a vein or in fatty tissue.

Who can participate?
Healthy adult volunteers aged 18 or older.

What does the study involve?
You will be randomly allocated into one of two groups. The doctor will place a needle superficially into your arm. In one group the needle will be inserted into a vein and in the other group the needle will be inserted into fatty tissue. The doctor will use an ultrasound probe to guide the puncture. During the puncture optical data is collected. This takes about 20 seconds. During these 20 seconds, you will be asked to move as little as possible. The procedure of inserting the needle and collecting the data will take about 5 minutes.

What are the possible benefits and risks of participating?
There is no direct benefit for the group of subjects; however, the results of this study may in future assist the improvement of regional anesthesia and interventional pain procedures. We do not foresee any major risks in participating in this study. You may experience some discomfort, similar to or less than the discomfort that you would experience during normal blood sample collection. You will receive a small but reasonable compensation for the potential discomfort.

Where is the study run from?
University Medical Centre Nijmegen (Netherlands).

When is the study starting and how long is it expected to run for?
From June to July 2011.

Who is funding the study?
Philips Healthcare (Netherlands).

Who is the main contact?
Dr Geert-Jan van Geffen
University Medical Centre Radboud, Nijmegen

Contact information

Type(s)
Scientific

Contact name
Dr Geert-Jan van Geffen

Contact details
Geert Grooteplein-Zuid 10
Nijmegen
Netherlands
6525 GA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PhN-11035

Study information

Scientific Title
Optical Tissue Stylet - randomized controlled trial into vascular access in humans

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CMO regio Nijmegen-Arnhem (Committee on Research involving human subjects, area Nijmegen-Arnhem), registration number: 2011/198, NL number: NL365280.091.11

Study design
Single-center single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Regional anesthesia

Interventions
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.

Intervention Type
Device

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2011

Completion date
05/07/2011

Eligibility

Key inclusion criteria
1. More than 18 years old
2. Healthy (category 1 of the ASA physical status classification system)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Pregnancy
2. Photodynamic therapy
3. Inability to give informed consent
4. Category 2 and higher of the ASA physical status classification system

Date of first enrolment
30/06/2011

Date of final enrolment
05/07/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Anesthesiology Department, University Medical Centre Nijmegen (UMC St. Radboud)
Geert Grooteplein 10
Nijmegen
Netherlands
6525 GA

Sponsor information

Organisation
Philips Healthcare

Sponsor details
Veenpluis 4-6
Best
Netherlands
5684PC

Sponsor type
Industry

ROR
https://ror.org/02p2bgp27

Funder(s)

Funder type
Industry

Funder Name
Philips

Alternative Name(s)
Koninklijke Philips N.V., Royal Philips, Royal Philips N.V., Philips & Co

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Publication is planned for Q2 of 2015

Intention to publish date
30/03/2015

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		09/03/2017	08/03/2023	No	No
Results article		09/03/2017	08/03/2023	Yes	No