Optical Tissue Stylet - observational study in humans

Published: 19-04-2010
Last updated: 19-03-2025

Aim of the study is to evaluate if the optical tissue stylet technology can discriminate tissues that are relevant to recognize for interventional pain procedures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Observational invasive

Summary

ID

NL-OMON34816

Source
ToetsingOnline

Brief title
OTS OS

Condition

- Spinal cord and nerve root disorders

Synonym
nerve pain

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: image-guidance, interventional pain procedure, needle placement, tissue identification

Outcome measures

Primary outcome

The primary objective of the trial is to explore differences in the optical signals obtained in tissues encountered along the needle trajectory during image-guided interventional pain procedures.
Therefore, successful acquisition of optical spectra at well-defined points during the image-guided interventional pain procedures is the primary study parameter.

The primary objective of the trial is to explore differences in the optical signals obtained in tissues encountered along the needle trajectory during image-guided interventional pain procedures.

Therefore, the primary study parameters are:
1. Successfully acquired diffuse reflectance spectra obtained in subcutaneous fat, muscle, fascia, and the adipose tissue surrounding the target nerve.
2. Confirmation images by ultrasound, fluoroscopy, and the electrical stimulation threshold levels obtained at the locations where the diffuse reflectance spectra have been collected
3. the *certainty score* on a 3-point scale 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 electrical stimulation

Secondary outcome

not applicable

Study description

Background summary

For effective interventional pain treatments, correct needle placement is crucial. Therefor, currently, needle placement is done under image-guidance, and the actual treatment location is confirmed with electrical stimulation before the treatment takes place. 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 patients. Special sterile optical tissue stylets have been made, that fit into the lumen of the needles that are normally used for treatment. A set of image-guided interventional pain procedures has been selected, during which diffuse reflectance spectra will be acquired with the optical tissue stylets, at a number of points along the needle trajectory that allow for confirmation by imaging and/or electrical stimulation.

We will investigate whether the optical tissue stylet technology provides information relevant for identifying specific tissue transitions. In case of positive results of this feasibility study, additional studies will be set up, for instance to explore whether providing the optical tissue stylet data to the physician during a procedure results in improved procedure outcome.

The procedures during which data will be obtained are currently common clinical practice. This study will not increase the number of interventional pain procedures performed or the number of patients undergoing a certain procedure, since subjects will be included who have been scheduled to undergo the selected procedure irrespective of the study.
During the observational study, data collected by the system will not be provided to the physician during the procedures, as we intend to influence the course of the procedure as little as possible.

Study objective

Aim of the study is to evaluate if the optical tissue stylet technology can discriminate tissues that are relevant to recognize for interventional pain procedures.

Study design

This is a nonrandomized controlled observational study, conducted in a single center to evaluate the potential of diffuse reflectance spectroscopy measurements to identify tissues at the tip of a needle during image-guided interventional pain treatments

Study burden and risks

The procedures during which data will be obtained are currently common clinical practice. During the observational study, data collected by the system will not be provided to the physician during the procedures, as we intend to influence the course of the procedure as little as possible. We foresee that in order to collect the diffuse reflectance spectra, it will be required to perform the procedures at a slower pace than normal. The expected maximum procedure lengthening is 20% of normal procedure duration, up to a maximum procedure lengthening of 5 minutes, which is clinically acceptable. Subjects who participate in the test will not be exposed to additional risks. They will experience minimal discomfort.

Contacts

Public
Philips

High TEch Campus 34
5656 AE
Nederland
Scientific
Philips

High TEch Campus 34
5656 AE
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients that fall into one of the following classes:
A. Neuralgia paraesthetica patients for whom the indication of a blockade of the nervus cutaneus femoris lateralis has been made.
B. Patients experiencing pain in the groin area, for whom the indication of a blockade of the nervus ilioinguinalis, nervus iliohypogastricus, or nervus genitofemoralis, nervus femoralis, nervus ischiadicus, nervus peroneus, nervus tibialis anterior, nervus saphenus, nervus suralis, nervus pudendus and has been made.
C. Patients experiencing pain in the arm and neck area, for whom the indication of a blockade of the nervus auricularis magnus and plexus brachialis (nn radialis, ulnaris, medianus) has been made.
D. Patients experiencing discogenic lower back pain, which have been indicated for a blockade of the communicating ramus.
E. Patients who have been indicated for a sympathetic blockade either because of a complex regional pain syndrome, or because of a peripheral vascular disease.

Exclusion criteria

- patients that undergo photodynamic therapy
- pregnancy

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):	11-06-2010
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	25-08-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 20744
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL31578.068.10
Other	nog niet bekend - registratie volgt na METC goedkeuring
OMON	NL-OMON20744