Photonic Needle and intraforaminal epidurale injection (sleeve) - observational study in humans (Sleeve 1 study)

Published: 17-10-2011
Last updated: 28-04-2024

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

Summary

ID

NL-OMON35392

Source
ToetsingOnline

Brief title
Sleeve 1 study

Condition

- Spinal cord and nerve root disorders

Synonym
nerve pain, radicular pain

Research involving
Human

Sponsors and support

Primary sponsor: Philips

Source(s) of monetary or material Support: door middelen van de industrie (Philips B.V.) en door personeel uit eigen budget.

Intervention

Keyword: image-guidance, interventional pain procedures, needle placement, tissue identification

Outcome measures

Primary outcome

The primary objective of this study is to investigate the potential of the photonic needle to discriminate between correct and incorrect placement of the needle tip in the target area of the procedure (M4 - tissue), as confirmed by contrast-enhanced fluoroscopy.

The main study parameters are:

1) Successfully acquired diffuse reflectance spectra obtained at measurement point M4: midforaminal, halfway the foramen (the target treatment location) as encountered during image-guided intraforaminal injections on lumbar level.

2) Confirmation of target area with fluoroscopy and injection of contrast fluid (gold standard).

3) *Certainty score* on a 3-point scale (1 = uncertain, 2 = certain, 3 = very certain) will be provided by the physician. The type of tissue present at the needle tip will be based on the information available from imaging.

Secondary outcome

The secondary objectives are to investigate the differences in the optical signals obtained with the photonic needle at a set of different pre-defined positions (M1, M2 and M3) encountered along the needle trajectory during

above-mentioned procedures, and to detect potential intravascular positioning of the needle-tip at the target point (M4 - blood).

The secondary study parameters are:

1) Successfully acquired diffuse reflectance spectra obtained at measurement points M1-M3: M1 in muscle, M2 extra-foraminal, M3 foraminal at a distance 1/3 of the diameter of the foramen from the entrance of the foramen, as encountered during image-guided intraforaminal injections on lumbar level.

2) Successfully acquired diffuse reflectance spectra obtained at measurement point M4, in case of a vascular puncture (M4-blood)

3) Confirmation images by ultrasound imaging at location M1 as described above.

4) Confirmation images by fluoroscopy at locations M2 and M3.

5) Digital subtraction angiography images after contrast injection at location M4, confirming vascular penetration (gold standard for vessel puncture).

6) *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 at M1 and at M4-blood.

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. The procedures during which data will be obtained are currently common clinical practice. This study will not increasethe 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

The primary objective of this study is to investigate the potential of the photonic needle to discriminate between correct and incorrect placement of the needle tip in the target area of the procedure (M4 - tissue), as confirmed by contrast-enhanced fluoroscopy.

Study design

This study will be a single blinded observational study in a limited number of patients.

Study burden and risks

In order to collect the data during the treatments, the treatments will take a bit longer than normal. The expected maximum procedure lengthening is 20% of normal procedure duration, up to a maximum of 5 minutes, which is clinically acceptable. Subjects who participate in the study will not benefit from the test nor be exposed to additional risks. They will experience minimal discomfort. In future, the results of this investigation may assist the improvement of 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

- Radicular pain
- Patients* age is 18-80 years
- Signed informed consent

Exclusion criteria

- Pregnancy
- Photodynamic therapy used before
- Inability to give informed consent
- Contrast fluid allergy
- Any operation on the spine at the side of intervention

- Coagulation disorders / disturbance
- Infections at the level of intervention

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):	25-10-2011
Enrollment:	33
Type:	Actual

Medical products/devices used

Generic name:	Photonic Needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-10-2011
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL37470.068.11