Laser Speckle Imaging of blood flow in the microcirculation of the cerebral cortex

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1. Protocol A: Laser Speckle Imaging (LSI) of blood flow changes coupled to neuronal activity in the human cerebral cortex: To investigate and optimize the use of LSI to visualize blood flow changes coupled to neuronal activity. The aim is to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36491

Source
ToetsingOnline

Brief title
Laser Speckle Imaging of cerbral cortex

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
function of the microcirculation in the cerebral cortex

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: imaging, Laser Speckle Imaging, microcirculation

Outcome measures

Primary outcome

The aim of the study is two-sided. First we propose to investigate and further develop the use of LSI to asses blood flow changes coupled to neuronal activities and to find out whether this approach can be used during tumor dissection. Secondly we aim to investigate the effects of several therapeutic standard interventions (infusion of mannitol, artificial elevation of mean arterial pressure and placement of surgical devices), which are expected to influence CBF, and are routinely used during neurosurgical procedures on microcirculatory flow in the brain, with and without the use of Transcranial Doppler Ultrasound to compare blood flow velocity in the microvasculature with the larger cerebral arteries.

Secondary outcome

nvt

Study description

Background summary

Imaging activities in the human brain form one of the major challenges in the field of neuroscience, and advances in this area will directly affect approaches in the fields of neurology and neurosurgery. To date, the methods for visualizing neuronal activity in humans suffer from several limitations. They either reflect differences in neuronal activity indirectly by measuring changes in vascular perfusion (fMRI and PET-scan), or they directly reflect neuronal electrical activity, but do not provide robust neuro-anatomical specificity (EEG and MEG). These technologies suffer respectively from

relatively limited temporal and spatial resolutions. Usually brain tumors are initially identified using standard MRI, and once the patient is subjected to neurosurgery, an attempt is made to obtain a total resection of the tumor with minimal loss of surrounding vital neuronal tissue, especially that of areas involved in pivotal functions such as speech and limb movements. The currently used golden-standard procedure for identifying functional regions surrounding the tumor is the electrocortical stimulation mapping (ECM) technique. Unfortunately, ECM has several disadvantages (risk of hemorrhage, seizures and time-consuming). Here, we provide an alternative by using the non-invasive Laser Speckle Imaging technique, a technique with a high spatiotemporal resolution for imaging local blood flow changes, which are known to be coupled to neuronal activity.

Study objective

1. Protocol A: Laser Speckle Imaging (LSI) of blood flow changes coupled to neuronal activity in the human cerebral cortex: To investigate and optimize the use of LSI to visualize blood flow changes coupled to neuronal activity. The aim is to identify and discriminate specific functions of vital neuronal tissue more precise, more efficient and faster as compared to current methods.

2. Protocol B: Effect of systemic medication on microcirculatory flow in the brain assessed by Laser Speckle Imaging (LSI): Evaluation of the effects of routinely used systemic medication and surgical devices (standard interventions during neurosurgical procedures) on the local microcirculation in parts of the cerebral cortex, with (not routinely used) and without the use of Transcranial Doppler.

Study design

The study design will be observational without invasive measurements. Recording will be made during taskperforming (in the awake craniotomy) and during the standard infusion of mannitol and phenylephrine as described in the protocol.

Study burden and risks

There will be no risks involving taking the measurements, it is a non-invasive method and the camera will stay approximately 30 centimeter above the cortex of the brain. The LSI measurements will take at most 15 minutes and are not painfull or dangerous. The measurements will not have a negative influence on the patient, the surgery or the surgeon. The surgeon will be monitoring the medical situation at all times.

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

All patients that will undergo an awake craniotomy will be eligible for protocol A. They have to be at least 18 years old and there has to be informed consent.
All patients that will undergo a craniotomy under anaesthesia are eligible for protocol B. They have to be at least 18 years old and there has to be informed consent.

Exclusion criteria

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Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-02-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL29227.078.09