MSOT beeldvorming in de onderbenen van gezonde vrijwilligers.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27078

Source
Nationaal Trial Register

Brief title
LOW-MSOT

Health condition

peripheral atheroslerosis.

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Deutsche Forschungsgemeinschaft

Intervention

Outcome measures

Primary outcome

Primary endpoints are to determine measurement variation (mean and SD) of MSOT in physiological perfused lower leg.

Secondary outcome

Information on safety aspects of the MSOT imaging device, side effects, adverse events (AE), serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR).

Study description

Background summary

The current project comprises a proof of principal study to test the technical feasability of the use of Multispectral Optoacoustic Tomography (MSOT) in healthy volunteers for non-invasive measurements and imaging of perfusion and oxygenation in the lower legs. MSOT is a non-invasive imaging modality that provides real-time quantifiable in vivo visualizations dependent on the intrinsic difference in optical absorption properties of tissues. MSOT uses pulsed laser light of various wavelengths to excitate the molecules in tissue. The excitated molecules generate a ultrasonic wave, which is detected by an ultrasonic detector. Unlike optical microscopy, optoacoustic imaging is not influenced significantly by light scattering in tissue, because it detects ultrasonic waves. This results in the ability to maintain a high resolution and quantifiability even at depths of 1.5-2 cm. The imaging system is essentially a laser and an ultrasound detector combined in a handheld probe which is connected to a computer for processing, and a display for real-time video-rate visualisation. By measuring peripheral blood oxygenation and perfusion with a prototype handheld MSOT probe and comparing that to standard ultrasound imaging, pulse-oximetry and standard ankle-brachial index as a gold standard, the diagnostic accuracy and measurement ranges in physiologic conditions as determined by MSOT will be tested.

Study objective

Evalueren wat de gevoeligheid van de MSOT techniek is voor het meten van de doorbloeding en de hoeveelheid zuurstof in de onderbenen van gezonde vrijwilligers

Study design

One time-point measurement after obtaining informed consent

Intervention

Measurement variation (mean and SD) of MSOT in the lower leg.
Correlation of MSOT oxygenation and perfusion measurements with standard ultrasound imaging of the fixed anatomical landmarks, pulse-oximetry data for oxygenation status at the hallux and the ankle-brachial index of the right lower leg.

Contacts

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Eligibility criteria

Inclusion criteria

Ten (10) healthy volunteers (5 males and 5 females), age >18 years will be asked to participate.

- No prior or current medication.

- Age >= 18 years.

- Written informed consent.

- Adequate potential for telephone follow-up 14 days following the measurement with MSOT.

Exclusion criteria

- Medical or psychiatric conditions that compromise the volunteers' ability to give informed consent.

- Concurrent uncontrolled medical conditions.

- Any investigational treatment for peripheral vascular disease or lower leg fractures within the past month.

- Pregnancy or breast feeding.

- Clinically significant (i.e. active) cardiovascular disease (e.g. congestive heart failure, symptomatic coronary artery disease and cardiac dysrhythmia, e.g. atrial fibrillation, even if controlled with medication, peripheral vascular disease) or myocardial infarction within the past 12 months.

- Patients with symptoms or history of peripheral neuropathy.

- (Partial) amputation of one of the legs.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3966
NTR-old	NTR4125
Other	: LOW-MSOT1.0
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A