The Feasibility of Multispectral Optoacoustic Tomography in different diseases: a phase 1 explorative imaging study

Published: 07-04-2020
Last updated: 27-12-2024

- The technical feasibility of multispectral optoacoustic tomography for the localization and assessment of disease-specific tissue in a particular anatomical area- Detection of endogenous biomarkers for the characterization in a variety of diseases...

Ethical review	Approved WMO
Status	Pending
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON49969

Source
ToetsingOnline

Brief title
FOMO

Condition

- Soft tissue neoplasms malignant and unspecified
- Skin neoplasms malignant and unspecified
- Vascular disorders NEC

Synonym
Cancer, peripheral arterial disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diagnosis, MSOT, optoacoustics, treatment monitoring

Outcome measures

Primary outcome

- The technical feasibility of optoacoustic imaging of disease-specific tissue

in different diseases

- Quantification of endogenous optoacoustic signals from various endogenous

absorbers as observed by the MSOT Acuity Echo.

Secondary outcome

-

Study description

Background summary

Optoacoustic imaging is a new and innovative imaging technique that combines the high contrast of optical imaging with the penetration depth and high spatial resolution of ultrasonography using the optoacoustic effect. It can resolve different endogenous tissue chromophores and may thereby provide insight in molecular changes associated with disease (-progression). It can be potentially used as an technique for diagnosis, treatment monitoring and disease localization. As the technique is relatively new in the clinical setting, there is not much clinical experience with optoacoustic imaging. The rationale for this study is to assess the technical feasibility of optoacoustic imaging in a variety of disease and to determine endogenous biomarkers for disease characterization for potential diagnosis and/or disease monitoring.

Study objective

- The technical feasibility of multispectral optoacoustic tomography for the

localization and assessment of disease-specific tissue in a particular anatomical area
- Detection of endogenous biomarkers for the characterization in a variety of diseases

Study design

The current study is a single center, prospective, cross-sectional, explorative study. The study procedures will be performed at the University Medical Center Groningen, Department of Nuclear Medicine and Molecular Imaging.

Study burden and risks

Burden
Patients will be imaged immediately after their appointment at the outpatient clinic. The patient will undergo one imaging moment of maximum 15 minutes, no other study related procedures will be performed. Healthy volunteers will undergo one imaging moment of 15 minutes.
Risks
A potential hazard of applying MSOT imaging is cornea damage, as well for the patient as the operator, which is taken care of by a laser safety Standard-Operating-Procedure as everyone present in the MSOT room is obligated to wear laser safety goggles. The residual risk of MSOT is slight, reversible reddening and temperature increase of the skin.
Benefit
Patients will have no direct benefit from this study.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients with the following diseases will be included:
a. Morbus Sjögren,
b. A superficially located malignant tumor < 5 centimeter beneath the skin
c. (Peripheral) arterial disease
2. Age >= 18 years;

Exclusion criteria

1. Patients with disease localizations or manifestations that do not enable good coupling between the optoacoustic probe and the skin, as decided by the researchers;
2. Medical or psychiatric conditions that compromise the patient*s ability to give informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-04-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	Clinical trials register nummer volgt
CCMO	NL71894.042.19