Imaging vascularisation and morphometry in burns and scars by Optical Coherence Tomography

Published: 04-02-2015
Last updated: 20-04-2024

To test the suitability of OCT for in vivo imaging of the vascularisation and surrounding tissue of burn wounds and scars.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40457

Source
ToetsingOnline

Brief title
Optical Coherence Tomography in burns and scars

Condition

- Epidermal and dermal conditions

Synonym
1. Vascularisation en morphometry of burns and scars 2. Imaging of blood flow and tissue structure

Research involving
Human

Sponsors and support

Primary sponsor: Brandwondencentrum
Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: Burn wounds, Optical Coherence Tomography, Scars, Vascularisation

Outcome measures

Primary outcome

The main study parameter is the utility of OCT to perform objective assessment of the vascularisation and surrounding tissue in burns and scars. Based on previous studies we expect to see a loss of layered structure in (deep) burn wounds and reduced to absent vascularisation. Moreover, a smaller birefringence and collagen denaturation can be found in thermally injured skin. To quantify the vascularisation in scars, we endeavour to identify the diameter of blood vessels and obtain vessel density .

Secondary outcome

- Scar: colour, elasticity, subjective scar outcome assessed by the POSAS.
- Burn wound: depth assessment by the clinical impression of an experienced burn clinician.

The secondary study parameters are not used for determination of the utility of OCT but may be used to perform additional analyses.
E.g.: assessing agreement between colour measurement and vessel density assessed by OCT.

Study description

Background summary

Vascularisation plays a key role in wound healing, scar formation, and reconstructive surgery. In burns, the wound healing potential is based on the depth of thermal injury and thereby on the residual intact vascularisation. Imaging of the vascularisation of the (burn) wound will aid the understanding of the healing potential and need for skin transplantation. Moreover, by objectification of the vascularisation network, the possibilities for scar evaluation will be optimized. For reconstructive procedures, improving the understanding of tissue vascularisation will improve the outcome of the surgery.

Non-invasive optical techniques that measure the vascularisation of the skin can therefore be of paramount value in improving the outcome of burn- and reconstructive surgery. One of the most promising optical techniques, Optical Coherence Tomography, will be tested in this research project.

Study objective

To test the suitability of OCT for in vivo imaging of the vascularisation and surrounding tissue of burn wounds and scars.

Study design

A pilot study will be performed in the Burn Centre of Beverwijk and the Plastic & Reconstructive Surgery department of the Red Cross Hospital in Beverwijk. Also, there may be patients included from the outpatient clinic. The study results will not be used for diagnostic or therapeutic purposes. The study is conducted to test the suitability of OCT in burn wounds and scars.

The accuracy of OCT will be tested by comparing the results of the measurement device with those obtained from histology, though histologic examination will be performed with residual tissue available from a planned operation. Additionally, on every included scar a validated subjective scar assessment scale (POSAS) will be used [van de Kar2005, Draaijers 2004a]. Furthermore, colorimetry (DSMII) and elasticity measurements (Cutometer) will be performed when possible [Draaijers2004c]. For burn wounds, subjective depth assessment will also be done by experienced burn clinicians. The measurements will be performed once on every patient, whereby no follow up is required. The total duration of this study is one year.

Study burden and risks

There is no potential benefit for patients participating in this study, but the experimental measurements may lead to an improved outcome in the future.

Burden:
- Single measurement with OCT during admission or outpatient clinic visit,

30-45 minutes
- In case of a scar: POSAS, elasticity and colour measurements, 15 minutes
- The measurements are carried out as much as possible during surgery. Measurements are also performed in intubated patients so that they suffer no discomfort. For this reason incompetent patients are included as well.
- Histological examination is performed with residual tissue available from a planned operation.

Risks:
- An OCT measurement does not involve additional risks.

The burden and risks for a patient participating in this study is minimal. Therefore we consider this study justifiable.

Contacts

Public
Brandwondencentrum

Vondellaan 13
Beverwijk 1942 LE
NL
Scientific
Brandwondencentrum

Vondellaan 13
Beverwijk 1942 LE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age > 18 years
Competent or temporary incompetent (because of sedation and/or intubation)
Acute burn wound and a planned operation of the burn wound or:
Burn scar and an already planned excision (operation) of the scar

Exclusion criteria

Language barrier
Pre-existing vascular problems both acquired (venous or arterial diseases) or congenital (such
as vascular malformations)
(Possible) pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Optical Coherence Tomography
Registration:	No

Ethics review

Approved WMO Date:	04-02-2015
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	17-03-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL46182.094.14