Photoacoustic imaging (PAI) of lymphatic vessels in secondary limb lymphedema, a feasibility study

Gepubliceerd: 30-06-2021 Laatst bijgewerkt: 19-03-2025

Technology based on photoacoustic properties can be used as an imaging technique to visualise lymphatic vessels and veins for purposes of lymphatic surgery.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26096

Bron NTR

Verkorte titel PAI lymph

Aandoening

Lymphedema

Ondersteuning

Primaire sponsor: Erasmus University Medical Center Rotterdam **Overige ondersteuning:** Lending of the device

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main outcome is the possibility of depiction lymphatic vessels and veins in two-

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dimensional images on locations with lymphatic vessels determined with NIRF-L and locations with dermal backflow and compare PAI and NIRF-L findings.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study: Secondary limb lymphedema is a debilitating condition often resulting from surgical or radiotherapeutic cancer treatment. Imaging of the lymphatic vessels is necessary for surgical planning of lympho-venous bypass (LVB) surgery to treat secondary lymphedema in patients that are refractory to conventional treatments. Indocyanine green (ICG) mediated near-infrared fluorescence lymphography (NIRF-L) is currently used to visualize lymphatic vessels and dermal backflow (i.e., lymphatic leakage into the interstitium), which indicates failure of the lymphatic systems to transport lymph fluid. NIRF-L suffers from several disadvantages, which limit the information that is needed to accurately determine if a patient is a candidate for surgery and choose the optimal site to perform an anastomosis. Photoacoustic imaging (PAI) is a promising imaging technique that can overcome several of these disadvantages.

Objective of the study: Explore the clinical feasibility of LED-based PAI of the lymphatic vessels and circulatory system in patients with secondary limb lymphedema.

Study design: This study is a prospective, researcher initiated, feasibility study. Study population: We will include patients referred to the plastic- and reconstructive surgery department for (potential) microsurgical treatment of secondary limb lymphedema of 18 years and older. In total, 10 patients will be included and imaged with the same imaging protocol.

Primary study parameters/outcomes: The main outcome is the possibility of depiction lymphatic vessels and veins in two-dimensional images on locations with lymphatic vessels determined with NIRF-L and locations with dermal backflow and compare PAI and NIRF-L findings.

Secondary study parameters/outcomes: Secondary parameters are: the depth and diameter of the lymphatic vessels and veins, possibility of depiction of lymphatic vessels and veins in three-dimensional images and the possibility to detect lymphatic vessels behind dermal backflow patterns.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation only takes ~30 minutes of a patient's time. Imaging will take place directly after NIRF-L, so no extra travel time is needed for the patients. There is no ICG injected for the purpose of this study, the ICG is injected before as a part of the regular imaging protocol. The imaging itself is not uncomfortable and comparable to regular ultrasound imaging. Residual risks associated with this are negligible. The participants will not have a direct benefit from participating, but this research contributes to improvements of surgical planning of LVB for the treatment of lymphedema.

Doel van het onderzoek

Technology based on photoacoustic properties can be used as an imaging technique to visualise lymphatic vessels and veins for purposes of lymphatic surgery.

Onderzoeksopzet

All patient characteristics (age, BMI, gender, limb circumference measurements and relevant medical history), NIRF-L and photoacoustic images are obtained on the same day during the patient's regular outpatient clinic visit. This is the only timepoint in this study. NIRF-L images are obtained with the photodynamic eye (Hamamatsu photonics) and photoacoustic images with the AcousticX (Cyberdyne INC.)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Over 18 years,
- · Secondary lymphedema as a result of cancer treatment,
- · Secondary lymphedema of one arm or leg,
- Willingness of participation: signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Presence of an allergic history for iodine,
- Patients where the standard imaging (near-infrared fluorescence imaging) cannot be performed,
- Active infection of the limb,
- Pregnancy (note: most patients will be beyond child bearing age)

Onderzoeksopzet

Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	04-11-2021
Aantal proefpersonen:	15
Туре:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling		
Positief advies Datum:	30-06-2021	
Soort:	Eerste indiening	

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Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49889 Bron: ToetsingOnline Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9595
ССМО	NL78365.078.21
OMON	NL-OMON49889

Resultaten