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

No registrations found.

Ethical review	Positive opinion	
Status	Recruitment stopped	
Health condition type	-	
Study type	Observational non invasive	

# **Summary**

### ID

NL-OMON26096

Source NTR

Brief title PAI lymph

**Health condition** 

Lymphedema

### **Sponsors and support**

Primary sponsor: Erasmus University Medical Center Rotterdam Source(s) of monetary or material Support: Lending of the device

### Intervention

#### **Outcome measures**

#### **Primary outcome**

The main outcome is the possibility of depiction lymphatic vessels and veins in twodimensional images on locations with lymphatic vessels determined with NIRF-L and locations with dermal backflow and compare PAI and NIRF-L findings.

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#### Secondary outcome

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

# **Study description**

#### **Background summary**

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.

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#### **Study objective**

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

#### Study design

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.)

# Contacts

#### Public

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# **Eligibility criteria**

### **Inclusion criteria**

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

### **Exclusion criteria**

- Presence of an allergic history for iodine,
- Patients where the standard imaging (near-infrared fluorescence imaging) cannot be

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performed,

- Active infection of the limb,
- Pregnancy (note: most patients will be beyond child bearing age)

# 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

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Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2021
Enrollment:	15
Туре:	Actual

### **IPD** sharing statement

Plan to share IPD: Undecided

# **Ethics review**

Positive opinion Date: Application type:

30-06-2021 First submission

# **Study registrations**

# Followed up by the following (possibly more current) registration

ID: 49889 Bron: ToetsingOnline Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

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

# **Study results**