Measuring lymph flow velocity in superficial lymph vessels using Transonic Transit Time Ultrasound Microvascular Flowprobe (AureFlo®), a pilot study

No registrations found.

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

Summary

ID

NL-OMON29245

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Lymphedema

Sponsors and support

Primary sponsor: Plastic Surgery MUMC+
Source(s) of monetary or material Support: Plastic Surgery MUMC+

Intervention

Outcome measures

Primary outcome

The main study endpoint is lymph flow velocity in the superficial lymphatic vessels in the

wrist/forearm in ml/min.

Secondary outcome

-

Study description

Background summary

Until now, the lymph flow could only be measured indirectly by calculating an average flow velocity over a certain distance (foot-inguinal or hand-axilla). With the invention of the Flowprobe for microsurgical vessels, flow can be measured quantitatively and directly. Early results from Chen et al. (2015) were promising, although only lymphedema patients were included in the study. Direct, local flow in healthy patients has not been described yet. The aim of this pilot study is to measure the lymph flow in the superficial lymph vessels of the upper extremity in healthy subjects to describe the lymph flow velocity in ml/min using Transonic Transit Time Ultrasound Microvascular Flowprobe (AureFlo®). The design of this study will be a descriptive pilot study. The duration of this study will be 18 to 24 months, in order to complete the measurements in 20 patients successfully. The study will take place in the Maastricht University Medical Centre. Twenty consecutive patients undergoing a free radial forearm flap reconstruction for any reason will be included if meeting the following criteria. Inclusion criteria: age > 18 years, absence of clinical lymphedema, indication for free radial forearm flap and no earlier operations or scars in that extremity at the level of wrist or forearm.
A potential subject who meets any of the following exclusion criteria cannot participate in this study: a history of lymphedema of any etiology, axillary lymph node metastases and history of axillary lymph node dissection. The main study endpoint is lymph flow velocity in the superficial lymphatic vessels in the wrist/forearm in ml/min.

Study objective

There is little known about lymph flow velocity in both healthy subjects and lymphedema patients. To understand lymphedema, we first need to know what is normal. This is the first time that lymph flow velocity is directly measured in healthy subjects.

Study design

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Contacts

Public
MUMC
Renée Miseré

0612764404
Scientific
MUMC
Renée Miseré

0612764404

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: age > 18 years, absence of clinical lymphedema, indication for free radial forearm flap and no earlier operations or scars in that extremity at the level of wrist or forearm.

Exclusion criteria

A potential subject who meets any of the following criteria cannot participate in this study: a history of lymphedema of any etiology, axillary lymph node metastases and history of axillary lymph node dissection.

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):	01-03-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	06-01-2020
Application type:	First submission

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	NL8268
Other	METC AZM/UM : METC 19-035

Study results