Validation of a Magnetic Resonance Lymphography protocol in upper extremity lymphedema and healthy subjects*

Published: 25-03-2020
Last updated: 10-04-2024

To determine the feasibility and applicability of the MRL protocol by comparing the images in upper extremity in patients with secondary lymphedema and healthy subjects, and to assess differences in the lymphatic system between the lymphedema…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spleen, lymphatic and reticuloendothelial system disorders
Study type	Observational invasive

Summary

ID

NL-OMON49628

Source
ToetsingOnline

Brief title
MRL in the upper extremity

Condition

- Spleen, lymphatic and reticuloendothelial system disorders

Synonym
edema of the arm, lymphedema

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lymphedema, Magnetic Resonance Lymphography, MRL, Upper Extremity

Outcome measures

Primary outcome

The primary outcome is to determine the feasiblity and applicability of the MRL protocol by evaluating the images of the upper extremity in patients with secondary lymphedema and healthy subjects. MRL images and 3D MIPs will be evaluated by an experienced radiologist and plastic surgeon and scored on the following points: qualitative and quantitative visibility of veins and lymph vessels, location, depth, (abnormal) pattern, diameter, and overall image quality on a scale of 10.

Moreover, differences in the lymphatic system between the lymphedema patients and healthy volunteers will be assessed.

Secondary outcome

The images and 3D MIPs will be compared with clinical staging according to the International Society of Lymphology (ISL) classification and Indocyanine green (ICG) lymphography. Clinical classification and ICG Lymphography is performed as standard care at the outpatient-clinic to evaluate lymphedema and as workup for surgical treatment. The dermal backflow stage, as described by, is used in the staging of lymphedema.

Study description

Background summary

Patients who do not benefit from conservative therapy, may need surgical intervention to relief symptoms, such as lymphaticovenous anastomosis (LVA). It is important to map the lymphatic system for diagnostic purposes and to evaluate which therapy has the greatest chance of succeeding. Imaging the lymphatic system is also useful for planning microsurgical lymphatic interventions. In contrary to the vascular system, the lymphatic system is difficult to visualize due to the fact that lymphatic fluid is not driven by a central pump. Therefore, lymphatic fluid has no continuous flow. Munn et al. (2014) discussed several techniques for visualization of the lymphatic system, including the MR Lymphangiography (MRL). They noted that the poor spatial resolution and sensitivity are limitations of MRL, but that further advancements of this technique may provide us with promising results for imaging the lymphatic system via MRL. Other authors have stated that MRL is a safe and feasible imaging technique for primary and secondary lymphedema. In the Maastricht University Medical Center the lymphatic system is pre-operatively visualized by a NIRF-camera for the more superficial lymphatic vessels and by lymphoscintigraphy for the deeper lymphatic system. Both lymphoscintigraphy and NIRF imaging have their limitations, such as poor resolution and depiction of only the superficial lymphatic system, respectively.

Study objective

To determine the feasibility and applicability of the MRL protocol by comparing the images in upper extremity in patients with secondary lymphedema and healthy subjects, and to assess differences in the lymphatic system between the lymphedema patients and healthy volunteers

Study design

Study design:
A validation study of an MRL protocol for the upper extremity with the Siemens 3Tesla Magnetom Prisma Fit at Scannexus, Maastricht.
All participants will undergo an MRL examination with the same protocol, developed in a previous *proof of principle* study, in the Maastricht University Medical Center+.

Duration of the study:
Inclusion will take 3 months. MRL scanning period will last for 3 months. Thereafter, data analysis will start.

Study burden and risks

The burden for the participants is a visit of approximately 2,5 hours. The MRL

examination will take around 2 hours. With explanation and preparations of 0,5 hours de visit will take 2,5 hours.

There are only small potential risks.
Gadolinium-based contrast agents are indicated for intravenous use in diagnostic MRI in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system. It is also used in MRL to visualize the lymphatic system.
In rare cases, the contrast agent (gadobutrol) might result in side effects, such as headache, nausea, injection site reaction, feeling hot, dizziness, and vomiting. It also increases the risk for nephrogenic systemic fibrosis among patients with severe kidney disease.
The recommended dose of gadobutrol is 0.1mL/kg body weight when injecting IV. In this study, we inject a maximum of 2-2.8 mL, intracutaneously.
Patients at risk (e.g. allergy for contrast agents, contraindications for MRI, such as renal insufficiency and claustrophobia) are excluded from the study to minimalize the chance of adverse reactions.
In previous studies, no adverse effects were reported regarding the MRL examination or contrast agent.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 years or older
- informed consent
- BMI < 30 kg/m2

Group A:
- Secondary lymphedema in the upper extremity
- conservative treatment with compression stockings and manual lymphatic drainage

Group B:
- Healthy volunteers

Exclusion criteria

- Active skin infection/erysipelas in the arm.
- Known allergy for a contrast agent
- History of surgical intervention in the arm.
- Contraindications for MRI with contrast; pregnancy, metals, prostheses, renal insufficiency, claustrophobia
- Active cancer
- Distant metastases

Study design

Design

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

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-09-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	25-03-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL72424.068.19