# Leg Muscle Metabolism Assessment in Critical Limb Ischemia with 7 Tesla MRI

Published: 21-01-2011 Last updated: 04-05-2024

To investigate whether 7T 31P magnetic resonance spectroscopy (MRS) provides an objective method to assess metabolic changes in response to ischemia in calf muscles of patients with critical limb ischemia (CLI) compared to healthy controls.Research...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

### Summary

#### ID

NL-OMON36666

**Source** ToetsingOnline

Brief title CLI and 7T 31P MRS

### Condition

• Arteriosclerosis, stenosis, vascular insufficiency and necrosis

#### Synonym

Critical limb ischemia / Peripheral arterial occlusive disease

#### **Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** Nederlandse Hartstichting & Stichting De Drie Lichten

### Intervention

Keyword: 7 Tesla MRI, Critical Limb Ischemia, Imaging, Spectroscopy

### **Outcome measures**

#### **Primary outcome**

Ad 1: Fifteen healthy controls will be subjected to a short period of unilateral arterial occlusion of the leg by supersystolic compression of the lower extremity arteries with an inflatable cuff. 7T 31P MRS will be performed before, during and after occlusion. Pi/ATP and PCr/ATP-ratios and pH will be compared between timepoints.

The fifteen healthy controls will be scanned on a separate occasion and results will be compared to test the test-retest reliability of the method.

Ad 2: Fifteen patients with proven chronic infra-popliteal CLI, who are not

candidates for surgical or radiological revascularization will undergo 7T 31P

MRS without applying arterial compression. Pi/ATP and PCr/ATP-ratios and pH

will be determined and compared to healthy controls with and without ischemia.

#### Secondary outcome

NA

# **Study description**

#### **Background summary**

Peripheral arterial disease (PAD) is a common cause of disability and mortality. In the last decade, therapies focusing on therapeutic neovascularization in cardiovascular diseases, ie the stimulation of new vessel formation have raised much interest. A drawback in studies that focus on such therapies is the lack of a valid and reliable objective perfusion measurement to evaluate the effects of such therapies. The ultra high magnetic field of a 7 Tesla (7T) MRI potentially provides the means for non-invasive assessment of functional and metabolic processes in the ischemic calf muscles of these patients. Phosphorus (31P) spectroscopy measures the tissue content of different 31P containing molecules that are involved in energy metabolism of the cells.

### Study objective

To investigate whether 7T 31P magnetic resonance spectroscopy (MRS) provides an objective method to assess metabolic changes in response to ischemia in calf muscles of patients with critical limb ischemia (CLI) compared to healthy controls.

Research questions:

(1) Can 7T 31P MRS determine metabolic changes in the calf muscle of healthy controls in response to short-lived lower limb ischemia assessed as changes in inorganic phosphate (Pi)/ Adenosine triphosphate (ATP) and phophocreatine (PCr)/ATP-ratios, and tissue pH?

(2) Can 7T 31P MRS identify differences in the spectroscopic profile in patients with chronic CLI as compared to healthy controls with and without ischemia?

### Study design

Non-interventional, cross-sectional, study.

### Study burden and risks

Patients will undergo a one hour pre-tested 7T MRI protocol. No contrast agents or other pharmacological substance will be administered. Yearly, more than 60 million studies are performed on 1.5T MRI platforms without significant negative side-effects. Up till now the amount of imaging studies performed on 7 or 8T MRI scanners is much smaller, but far over 1000 subjects have been scanned without clinical significant adverse effects.

# Contacts

**Public** Universitair Medisch Centrum Utrecht

Heidelberglaan 100 3584 CX Utrecht NL **Scientific** Universitair Medisch Centrum Utrecht

3 - Leg Muscle Metabolism Assessment in Critical Limb Ischemia with 7 Tesla MRI 13-05-2025

Heidelberglaan 100 3584 CX Utrecht NL

### **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

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

### **Inclusion criteria**

Inclusion criteria:

- Age > 18 years;

- Severe infra-popliteal PAOD (Fontaine class III and / or IV); Fontaine III: persistent, recurring rest pain requiring analgesia; Fontaine IV: non-healing ulcers present for > 4 weeks without evidence of improvement in response to conventional therapies

- Ankle brachial index < 0.6 or unreliable (non-compressible or not in proportion to the Fontaine classification);

- Written informed consent. ;The criteria apply to patients. Healthy controls may be included if they are above 18 years and have no signs of PAOD.

### **Exclusion criteria**

Exclusion criteria:

-Pregnancy

-Ineligible for scanning in the 7T MRI: subjects with cardiac pacemakers, claustrophobia, or metallic objects, i.e. stents, surgical clips etc. and all patients with bio-implants not explicitly indicated as safe to 7T MRI (see: mrisafety.com).;The abovementioned criteria apply to both patients and healthy controls.

# 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:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2011
Enrollment:	30
Туре:	Actual

# **Ethics review**

Approved WMO	21 01 2011
Date:	21-01-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	24-06-2011
Application type:	Amendment

# **Study registrations**

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

No registrations found.

5 - Leg Muscle Metabolism Assessment in Critical Limb Ischemia with 7 Tesla MRI 13-05-2025

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

No registrations found.

### In other registers

Register

ССМО

ID NL33906.041.10