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

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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

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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
Type:	Actual

Ethics review

Approved WMO 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
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL33906.041.10