Magnetic resonance Imaging techniques in patients with Refractory Critical Limb ischemia

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A study to explore three different diagnostic tools (predictors) (tcPO2 measurement, BOLD MRI and DCE MRI) quantifying the degree of tissue perfusion and oxygenation at the intended amputation level in patients with refractory critical limb ischemia...

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

Summary

ID

NL-OMON44605

Source
ToetsingOnline

Brief title
MIRaCLe study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
CLI, PAD

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BOLD MRI, DCE MRI, Magnetic resonance imaging, Refractory critical limb ischemia

Outcome measures

Primary outcome

Primary endpoints are:

• Signal-to-noise ratio (SNR) for each MRI technique. SNR of the MRI image and the SNR of the derived perfusion graphs.

• Inter observer calculations of the two MRI techniques. Intraclass correlation coefficient (ICC) is calculated for two observers both independently delineating regions of interests for calculation of perfusion graphs.

• Discriminative value - calculation of correlation values of measurement and image parameters with the three study groups (Spearman correlation).

Secondary outcome

To assess the level of discomfort of the different techniques in patients with and without critical ischemia.

Study description

Background summary

Patients with end-stage ischemic limb disease undergoing acute below knee amputation are most often condemned to a wheel chair leading to a significant impairment of physical fitness and quality of life. Instead of treating these frail elderlies in a very conservative manner leading to physical deterioration, we are now able to achieve immediate walking after amputation with a primary osseointegration prosthesis. Although large in number, limb loss due to refractory critical limb ischemia is always considered a contraindication for this osseointegration procedure as the lack of vascularization may cause (a)septic loosening of the implant. There is no

scientific evidence that refractory critical limb ischemia is a strict contraindication for an bone anchored osseointegration prosthesis. Recently a study was published about save and successful implantation of osseointegration prosthesis in five below knee amputees with refractory critical limb ischemia. The estimated chance of primary wound healing after a below knee amputation in a patient with refractory critical limb ischemia is an important condition for the implantation of an osseointegration prosthesis. To date an accurate predictor for successful primary wound healing after below-knee amputation is lacking.
In this study, we will compare three predictors for successful primary wound healing after below-knee amputation. These predictors are measures for lower limb tissue blood perfusion: 1. transcutaneous oxygen measurement (tcPO2), 2. Blood Oxygenation Level-Dependent (BOLD) MRI and 3. dynamic contrast-enhanced (DCE) MRI. The results of this explorative study will be used for a subsequent clinical trial in which the value of tcPO2, BOLD MRI and/or DCE MRI will be evaluated in what manner these predictors are useful to predict primary wound healing after below knee amputation and direct implantation of an osseointegration prosthesis in patients with refractory critical limb ischemia.

Study objective

A study to explore three different diagnostic tools (predictors) (tcPO2 measurement, BOLD MRI and DCE MRI) quantifying the degree of tissue perfusion and oxygenation at the intended amputation level in patients with refractory critical limb ischemia. The techniques will be compared with regard to signal to noise ratio, interobserver variability and discriminatory ability.

Study design

Explorative MR imaging study of approximately 3 months. Transcutaneous oxygen pressure measurements are performed on all subjects. Perfusion measurements are performed on all subjects with two different techniques: BOLD MRI and DCE MRI.

Study burden and risks

The burden for participants in this study will be between 45 and 60 minutes for the measurements of tcPO2 and MRI imaging procedures. Despite the exclusion of patients who cannot lie still for 15 minutes (time for each MRI sequence) in case of rest pain, some patients may experience some discomfort related to rest pain during cuff inflation. Patients can abort and withdraw at any time during the MR procedure.
For the DCE-MRI an intravenous drip with contrast is used with the following possible complications:

• Low possibility of complications due to the intravenous drip are: infection, phlebitis and thrombophlebitis, emboli, pain, haematoma or haemorrhage,

extravasation, arterial cannulation.
• Low possibility of complications due to the contrast agent are: Headache, nausea, vomiting, feeling unwell, dizziness, abnormal or unpleasant taste in your mouth, feeling hot, numbness or tingly feeling, itching or rash, skin redness, injection site reactions.

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

Informed consent
Age >= 16 years
Ability to lie still for 15 minutes without rest pain.

Exclusion criteria

Acute limb ischemia
Earlier bypass surgery at the side of imaging
Any intravascular stent in the femoral artery at the side of imaging
MR related exclusion criteria

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2018
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL63592.091.17