Blood oxygen level dependent (BOLD) magnetic resonance imaging technique to predict buttock claudication in patients undergoing endovascular abdominal aorta aneurysm repair (EVAR) with coiling of the internal iliac artery.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON49776

Source
ToetsingOnline

Brief title
BOLD BUTTOCK study

Condition

- Aneurysms and artery dissections

Synonym
gluteal ischemia, Pelvic ischemia

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Eureka Eurostars project (SPECTRE)

Intervention

Keyword: buttock claudication, EndoVascular Aorta Repair (EVAR), internal iliac artery coiling, MRI

Outcome measures

Primary outcome

Primary study outcomes are the BOLD-signal specific outcomes. These parameters

give an indication of the reserve and recovery capacity of the blood supply to

the gluteal muscles. Furthermore, the presence or absence of buttock

claudication will be monitored to correlate the BOLD-signal parameters with and

to determine the predictive value of the technique.

Secondary outcome

n.a.

Study description

Background summary

20% of patients with an abdominal aneurysm have a concomitant aneurysm in the iliac arteries. To enable a safe landing zone and prevent endoleaks, coiling of the internal iliac artery is indicated. This coiling, however, leads to persistent buttock claudication in 30% of the patients due to a deprived blood supply. A correct prediction of the chance of buttock claudication can be incorporated in the treatment to improve patient care. Currently, no predictive methods for buttock claudication are available. The MR techniques which will be investigated in this study might be useful predicting buttock claudication due to coiling of the internal iliac artery.

Study objective

The goal of this study is to investigate whether BOLD MRI can predict the occurrence of buttock claudication after coiling of the internal iliac arty.
The BOLD technique will be used to measure blood supply parameters of the gluteal muscle during and after ischemia of the muscle. The measured parameters will be correlated with the occurrence of buttock claudication.

Study design

Explorative MR imaging study by measuring BOLD-signal after induced ischemia. The study is divided into two sub-studies. Sub-study 1 investigates the predictive value of a non-invasive technique to acquire the BOLD-signal and will be a cross-sectional cohort study. Sub-study 2 investigates the predictive value of an invasive technique to induce the BOLD-signal and is designed as an observational prospective cohort study.

Study burden and risks

The burden and risk of this study for the patient is minimal.
The patients and volunteers in sub-study 1 will receive an MRI scan for a maximum of 30 minutes, where they are asked to actively contract the gluteal muscle for 4 times 30 seconds alternated by 15 seconds of rest. Especially patients with buttock claudication may experience discomfort during the contraction. They can stop the contraction whenever the discomfort is too high, afterwards symptoms will diminish. Patients are asked to fill in two questionnaires to score the extend of buttock claudication

The 10 patients scheduled for EVAR with coiling from sub-study 1 will also participate in sub-study 2. The artery occlusion and MR scan will be performed under general anesthesia. The patient will be transferred between two adjacent rooms, increasing anesthesia time with approximately 45 minutes. Furthermore, they should also fill the two questionnaires after 3 and 12 months.

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

group 1: 5 patients 1 year or longer after EVAR with coiling of internal iliac artery and with persistent buttock claudication
group 2: 5 patients 1 year or longer after EVAR with coiling of internal iliac artery and without persistent buttock claudication
group 3: 10 patients scheduled for EVAR with coiling of internal iliac artery
group 4: 10 volunteers without intermittent claudication

Exclusion criteria

Claustrophobia for MRI
<18 years old
No informed consent
Symptomatic- or ruptured aneurysm
MR related exclusion criteria

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):	11-06-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	25-05-2020
Application type:	First submission
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

ID: 27776
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL72133.091.19
OMON	NL-OMON27776