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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27776

Source NTR

Brief title BOLD Buttock

Health condition

Buttock claudication after overstenting of internal iliac artery

Sponsors and support

Primary sponsor: Radboudumc Source(s) of monetary or material Support: Eureka Eurostars

Intervention

Outcome measures

Primary outcome

BOLD MRI signal parameters at day 1. Presence or absence of buttock claudication at day 1, after 3 and after 12 months

Secondary outcome

Safety of the procedure

Study description

Background summary

Endovascular aorta repair (EVAR) has become the treatment of first choice for patients with an aneurysm of the abdominal aorta. In the Netherlands, approximately 3100 (75%) patients will be treated using the EVAR-procedure each year. Up to 20% of these patients have a concomitant aneurysm of the common iliac artery. For adequate prevention of the aneurysms, occlusion (by coiling or plug placement) of the ipsilateral internal iliac artery is required. Approximately, 30% of patients have long-term, persisting buttock claudication. No predictive tests exist to provide an adequate estimation of the risk of persisting buttock claudication after internal iliac artery occlusion. Our group developed (non-)invasive tests using blood oxygen level dependent (BOLD) magnetic resonance imaging (MRI) techniques. Within this study, feasibility for predicting buttock claudication using the different tests will be evaluated.

Study objective

The blood oxygen level dependent MRI signal can be used to predict buttock claudication after coiling of the internal iliac artery

Study design

BOLD-parameters at day 1.

Questionnaires to score buttock claudication: Walking impairment questionnaire, vascular quality of life questionnaire, Questionnaire for objectifying buttock claudication answered at day 1, after 3 months and after 12 months

Intervention

Inducing hypo, and hyperaemia in the gluteus maximus muscle by temporally occluding the internal iliac artery or by gluteus maximus muscle activation. The changing oxygen levels during both tests will be monitored using the BOLD MRI sequence

Contacts

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Eligibility criteria

Inclusion criteria

Patients scheduled for elective EVAR with internal iliac artery coiling Iliac branched device placement not possible for technical reasons of pre-existing buttock claudication

Exclusion criteria

Claustrophobia for MRI <18 years old No informed consent Symptomatic- or ruptured aneurysm Claustrophobia (regarding small MR bore) Pacemaker Non-MRI compatible implants

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	30
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	30-07-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49776 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8810
ССМО	NL72133.091.19
OMON	NL-OMON49776

Study results