Diagnostic value of distention and intima-media thickness measurement for the detection of endofibrosis and a possible role of the coagulation activation potential on the development of endofibrosis.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23772

Source
Nationaal Trial Register

Health condition

Coagulation, Endofibrosis, Intima-Media Thickness, vessel wall

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Kootstra Talent Fellowship

Intervention

Outcome measures

Primary outcome

Determining the IMT of the common iliac artery wall.

Determining the distension of the pelvic arterial wall.

Determine coagulation parameters

Secondary outcome

x

Study description

Background summary

Endofibrosis is an disease affecting 15-20% of the young (17-30 years old) professional cyclists and speed skaters. The disease is characterized by fibrotic tissue formation in the iliacal artery, resulting in a stenosis. As a result of this the bloodflow is reduced, resulting in unilateral ischemic symptoms.

To date the mechanism behind this fibrotic tissue formation is still unknown. However, the development of the fibrotic tissue formation is linked to activation of Protease Activated Receptors (PARs) by active coagulation factors. It's known that activation of these receptors by active coagulation factors can affect the vessel wall composition, however data is fragmented and the underlying mechanism is not known yet. So information about this could provide new insights in these processes and it can possibly be linked to the development of endofibrosis.

Endofibrosis is irreversible, so an surgical intervention is needed to solve the problem. Endofibrosis is with the current diagnostic methods (Duplex and Magnetic Resonance Angiography) only detectable in an late phase of the disease, when the patient already experiences significant symptoms. Recently a new diagnostic method is developed, with which vessel wall changes can be detected in an earlier stage. This method is based on intimal-media thickness (IMT) en distention measurement of the vessel wall by echography.

Since recent research found a new therapeutic target to inhibit fibrotic tissue formation in an early stage, early detection of the disease plays an important role to set up an noninvasive therapy.

Study objective

Can IMT and Distension measurment of the iliacal artery determine Endofibrosis in an early stage and is there a link between the development of endofibrosis and the coagulation activation potential of the blood?

Study design

x

Intervention

Ultrasound of the iliacal artery

Blood collection from the forearm (30mL)

Contacts

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Eligibility criteria

Inclusion criteria

Controle population: minimal 18 years old and max 35 years old - mentally capable

Population with endofibrosis: - minimal 18 years old and maximal 35. - mentally capable - complaining of lower limb ischemia during exercise - confirmed endofibrosis by Magnetic Resonance Angiography.

Exclusion criteria

All population: diagnosed with an cardiovascular disease, operation on the a. iliacal communis or a. iliacal externa, BMI > 30, <18 years old, pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	70
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4634
NTR-old	NTR4786
Other	:

Study results

Summary results
Posthuma JJ et al. Cycling induces a hypercoagulable state through contat activation.