The HIRADO study: Hand Ischemia and function after RADial artery Occlusion study

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to determine if exercise induced ischemia of the hand is present and if exercise induced ischemia of the hand leads to functional problems in patients with RAO

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46016

Source
ToetsingOnline

Brief title
Evaluation of Radial Occlusion

Condition

- Coronary artery disorders
- Vascular injuries

Synonym
Occlusion of the arm vessel, radial artery occlusion

Research involving
Human

Sponsors and support

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

Intervention

Keyword: lactate, occlusion, Radial artery, transradial intervention

Outcome measures

Primary outcome

Hand ischemia will primarily be evaluated with measurement of thumb capillary lactate changes after manual stress testing, and secondary, with changes of thumb transcutaneous partial pressure of oxygen.

Secondary outcome

Functional capacity of the hand will be evaluated by handgrip strength, sensibility of the hand and the QuickDASH questionnaire. The outcome parameters will be compared between patients with and without RAO.

Study description

Background summary

Despite the benefits of transradial access, complications do occur and became more apparent when implemented in a real world clinical setting. Radial artery occlusion (RAO) is the most common complication (5 up to 38%) but rarely leads to major ischemic events due to the collateral perfusion of the hand. However, it has been reported that radial artery occlusion can become symptomatic, possibly as a consequence of hand-ischemia. This may compromise upper limb function, however, this has not been evaluated in a large group of patients. We therefore initiated a multicentre observational study to evaluate the clinical consequences of RAO.

Study objective

to determine if exercise induced ischemia of the hand is present and if exercise induced ischemia of the hand leads to functional problems in patients with RAO

Study design

This is a multi center, observational clinical trial. After a transradial coronary procedure, patients with suspicion of RAO will be asked to participate. After informed consent signs of hand ischemia will be evaluated and functional capacity. 6 month follow up will be performed by telephonic interview; a subpopulation will undergo repeat testing during a follow-up visit at 6 months.

Study burden and risks

Patients are not at risk during this observational study, all test, except for thumb lactate measurements (obtained by fingersticks) are non-invasive. Patients will have some time burden (approximately 180-200 minutes) for undergoing all tests. There is no direct benefit for the patients, he study is designed to gain knowledge about the sequel of radial artery occlusion.

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

Patients who have undergone a previous TR procedure with a suspected RAO (defined as no radial artery pulse or no flow at ultrasound examination)

Exclusion criteria

1. Unable or not willing to give informed consent
2. Hemodialysis patients with an arteriovenous fistula

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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2016
Enrollment:	327
Type:	Actual

Ethics review

Approved WMO

Date:	20-07-2016
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL56364.029.16