ANTARCTICA: analysis using novel signaling pathway and 3-tesla imaging of arteriogenesis in chronic total occlusive coronary arteries

Published: 13-03-2013
Last updated: 24-04-2024

In this study we aim to develop new methods of non-invasive detection of collateral vessels with MRI, along with identifying novel therapeutic targets to influence arteriogenesis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON41624

Source
ToetsingOnline

Brief title
ANTARCTICA

Condition

- Coronary artery disorders

Synonym
chronic total occlusion/ chronic total coronary occlusion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Center for

translational molecular medicine (CTMM) ,Center for translational molecular medicine (CTMM) en Nederlandse Hart Stichting (NHS),Nederlandse Hartstichting

Intervention

Keyword: arteriogenesis, chronic total occlusion, collateral perfusion, MRI

Outcome measures

Primary outcome

Correlation between the intracoronary derived parameters and cardiac MRI

estimates of collateral coronary circulation.

Secondary outcome

Identification of genetic predispositions in patients with varying degrees of

collateralization, in order to ultimately identify novel therapeutic targets.

Study description

Background summary

Many clinical studies have implicated a functional significance of collateral arteries in relation to preserving left ventricular function, reducing infarct size and lowering future adverse cardiac events. Chronic total occluded coronary arteries (CTO; chronic total occlusion) offer the unique opportunity to measure collateral dependent perfusion. The current gold standard for quantitative assessment of the human coronary collateral circulation is by invasive cardiac examination. Based on such hemodynamic parameters, we propose to identify genetic predispositions in patients with varying degrees of collateralization, in order to ultimately identify novel therapeutic targets.
New avenues for collateral vessel growth also require sufficient means of collateral vessel detection. Among the non-invasive diagnostic imaging systems, MRI has been deemed as having the greatest versatility with regards to vascular imaging due to its capacity to obtain morphologic and functional information (Oostendorp et al. Radiology 2009; 251: 317-35). MRI has the capacity to visualize vessel growth at varying spatial and temporal scales, with greater sensitivity to small vessel function than other imaging modalities (Padhani. J Magn Reson Imaging 2002; 16: 407-22). These capabilities could prove to be advantageous for collateral vessel detection. There is a relative lack of data correlating the intracoronary derived pressure-derived collateral flow index

(CFIp) and velocity-derived collateral flow index (CFIv) and MRI derived estimates of collateral coronary circulation. Therefore the goal of this trial is to study this correlation between these intracoronary derived parameters and cardiac MRI estimates of collateral coronary circulation.

Study objective

In this study we aim to develop new methods of non-invasive detection of collateral vessels with MRI, along with identifying novel therapeutic targets to influence arteriogenesis.

Study design

Multicenter observational prospective study

Study burden and risks

Burden:
-time:
1 time MRI of approximately 45-60 minutes. Procedure time is extended with 15 minutes.

Risk:
The risk of complications during intracoronay measurements is small in the hands of experienced operators.
The radiation exposure is extended with 3 minutes.

Benefit:
No personal benefit for the included patients

Group Benefit:
-after completion of this study, the patients benefit lies in less need of invasive measurements by means of cathaterization as cardiac MRI can be used for determination of collateral function. This is of great importance in case of monitoring future therapies for arteriogenesis.

-furthermore, genetic factors could be identified which can be therapeutic targets for influencing arteriogenesis.

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 with a chronic total occlusion, in whom there is a clinical indication for CTO revascularization by means of PCI.

Exclusion criteria

- known MRI contrast allergy
-contra-indication for MRI
- previous transmural infarction in the area of the CTO, diagnosed on ECG or MRI -
- previous bypass cardiac surgery
-cardiac arrhythmia limiting flow velocity measurements
- congestive heart failure -
- clinical or laboratory signs of acute or chronic inflammatory illness
- impaired renal function (GFR < 30 ml)
- overt neoplastic disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	13-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-09-2014
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	NL43299.018.13