Remodeling of distal coronary vessel in chronic total occlusions: prediction based on hemodynamic coronary parameters

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To establish baseline predictive factors for acute and late lumen growth after successful opening of chronic total occlusions. Secondary objectives are:1) Identifying the relation between change in absolute microvascular resistance and late change...

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

Summary

ID

NL-OMON51242

Source
ToetsingOnline

Brief title
CTO-VR

Condition

- Coronary artery disorders

Synonym
Chronic Total Occlusie, coronary artery disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CTO-vessel, Parameters, Prediction, Remodeling

Outcome measures

Primary outcome

1) Changes in mean lumen diameter of the treated vessel, measured up to 5 mm distal to the stent after recanalization and at 3 months follow-up

2) Changes in mean lumen diameter of the treated vessel, measured up to 5 mm distal to the occlusion before recanalization and distal to the stent after recanalization

3) Changes in collateral function, using the equation ((Pw-Pv))/((Pa-Pv)), in rest and hyperaemic state, measured before recanalization, after recanalization and at 3 months follow-up.

Secondary outcome

1) Changes in microvascular resistance after recanalization and at 3 months follow-up

2) Stent malapposition at 3 months follow-up

3) Changes in the scoring of the SAQ before recanalization and at 3 months follow-up

Study description

Background summary

Revascularization of a chronic total occlusion (CTO) has gained popularity last decade. After recanalization there is an acute gain in vessel diameter, as well as a late lumen gain distal to the stent as a result of positive remodeling.
The evolution of a recanalized CTO-vessel is however diverse. Several studies

are performed to measure distal lumen gain and hemodynamic coronary parameters of a recanalized CTO, including the novel measurement Absolute Flow. Although the results seem promising, an association between those parameters and distal vessel lumen gain has never been found. Therefore, the aim of this study is to understand the remodeling of the distal coronary vessel in relation with hemodynamic coronary parameters, establishing baseline predictive factors, adding new information about coronary physiology.

Study objective

To establish baseline predictive factors for acute and late lumen growth after successful opening of chronic total occlusions.

Secondary objectives are:
1) Identifying the relation between change in absolute microvascular resistance and late change distal lumen diameter from the end of the index procedure to 3 months follow-up
2) Identifying the relation between late lumen growth and stent malapposition, assessed using Optical Coherence Tomography (OCT)
3) Identifying the relation between angina-related symptoms, assessed using the Seattle Angina Questionnaire (SAQ), and absolute microvascular resistance.

Study design

A single-center, prospective, observational cohort study. The center performing this study will be the Radboudumc.

Study burden and risks

Participants scheduled for revascularization of a CTO, receive standard care. Complications as a result of coronary angiography performed at 3 months follow-up are limited. The complication rate of the additional measurements is low. Therefore, the additional measurements are considered low risk. On the other hand, this study may provide valuable information on changes of procedural success.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Scheduled elective revascularization procedure of a CTO, defined as a complete obstruction of a coronary artery with TIMI-0 or TIMI-1 flow and occlusion duration of at least 3 months
- Heart-team consensus for the indication of a CTO treatment, based on viability and ischemia testing (using TTE or MRI)
- Able to give valid, written informed consent

Exclusion criteria

- Unsuccessful crossing of the lesion during PCI
- Renal insufficiency defined as eGFR < 30 ml/min
- Contra-indications to intravenous adenosine
- < 18 years of age
- Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-12-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	19-05-2021
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

No registrations found.

In other registers

Register	ID
CCMO	NL76417.091.21