Use of physiology to evaluate procedural result after PCI CTO

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Primary objective: -To assess the predictive value of post-PCI RFR (resting full-cycle ratio) and FFR (fractional flow reserve) with regard to SSR (suboptimal stent result) in CTO (chronic total occlusion) patients. Secondary objectives:- To assess...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON51148

Source
ToetsingOnline

Brief title
ULTRA-CTO STUDY

Condition

- Coronary artery disorders

Synonym
Chronic total occlusion, coronary artery occlusion

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Abbott,Isala klinieken;Zwolle

Intervention

Keyword: chronic total occlusion, intra-coronary physiology, optical coherence tomography, percutaneous coronary intervention

Outcome measures

Primary outcome

The AUC of post-PCI RFR (resting full-cycle ratio) compared to the AUC of

post-PCI FFR (coronary flow reserve) with regard to SSR (suboptimal stent

result).

Secondary outcome

Secondary endpoints are defined as:

- The predictive value of the RFR and FFR gradient across the stented segment

with regard to SSR in CTO patients.

- The correlation between positive RFR (<=0.89) and positive FFR (<=0.80)

following angiographically satisfactory CTO PCI.

- The correlation between post-PCI physiology (RFR, FFR, CFR, IMR) and SSR with

anginal complaints (SAQ score), NYHA and CCS classification and MACE at

follow-up.

- The correlation between OCT and/or physiology findings and physician-decision

making (perform or refrain from additional PCI)

Study description

Background summary

It is known that a suboptimal stent result (SSR) can lead to future PCI's .This is already the case for SSR after regular PCI's, however could be even more evident for SSR after a CTO PCI.

SSR is not always visible on a normal coronary angiogram. However, early detection of a SSR and accordingly direct optimization of the stent result can lead to a better and more sustainable result. The aim of this study is to investigate if performance of post-PCI coronary physiology measurements, including RFR (resting full-cycle ratio), FFR (fractional flow reserve), IMR (index of microcirculatory resistance) and coronary flow reserve (CFR) and the addition of OCT (optical coherence tomography), will detect SSR and lead to a better understanding of the functional and anatomical aspects of CTO PCI to guide further optimization of procedural results. The pressure wires and OCT camera that are used for the study-related measurements are commonly used interventional tools.

Study objective

Primary objective:
-To assess the predictive value of post-PCI RFR (resting full-cycle ratio) and FFR (fractional flow reserve) with regard to SSR (suboptimal stent result) in CTO (chronic total occlusion) patients.

Secondary objectives:
- To assess the predictive value with regard to SSR of the RFR and FFR gradient across the stented segment
- To evaluate the correlation between positive RFR (<=0.89) and positive FFR (<=0.80) with regard to SSR following angiographically satisfactory CTO PCI.
- To evaluate the correlation between post-PCI physiology (RFR, FFR, CFR, IMR) and SSR with anginal complaints (measured using the Seattle Angina Questionnaire [SAQ]), cardiovascular events and other clinical classifications (CCS and NYHA)
- To assess the impact on physician-decision making based on OCT and physiology findings.

Exploratory objective:
- To assess the change in RFR, FFR and other physiological parameters over time (subset of patients)

Study design

Prospective, multicentre, non-randomised investigator-initiated trial with a non-inferiority design.

Intervention

After angiographically successful PCI of the CTO target vessel (no remaining lesion proximal or in-stent >= 30%, confirmed in two orthogonal projections with an angle >=25 degrees apart), physiologic measurements must be performed in this vessel: Pd/Pa (pressure-distal / pressure-aorta = ratio of mean resting distal

coronary pressure to aortic pressure), RFR (resting full-cycle ratio), CFR (coronary flow reserve), IMR (index of microcirculatory resistance), FFR (fractional flow reserve). Additional OCT will be performed during the index procedure to assess the anatomic stent result. OCT may also be performed during a staged procedure within 4 ± 2 weeks when indicated (i.e. high contrast use, procedural duration, major dissection or other safety reasons according to the operator). For patients with a remaining intermediate stenosis (angiographically 30-90%) in a non-CTO vessel or major side branch of the CTO vessel with diameter >= 2mm, clinically indicated FFR guided PCI will be planned within 4 ± 2 weeks. During this staged procedure, intra-coronary physiologic assessment (RFR, FFR, CFR and IMR) will be repeated in the CTO vessel for exploratory objectives (before additional PCI).

Study burden and risks

PCI and medical treatment will be performed according to the international guidelines. The anticipated benefit is improvement of our knowledge on how to optimize stent results in CTO PCI. Because the pressure wires and OCT camera that are used for the study-related measurements are commonly used interventional tools, this poses no study-related additional risk for participating patients. Due to study-related measurements both procedures (as part of standard care) will be moderately prolonged, most likely by approximately 15 minutes. Patients will not be exposed to extra visits. Based on the available data we consider the risks and burden of this research project to be small. With minimal effort and risk, subjects included in this trial are able to contribute to research to that may improve the treatment of CTOs, which may have large impact on clinical practice and guidelines. This study will be conducted in full compliance to the principles of the Declaration of Helsinki.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Age 18 years and older.
2) Angiographically successful PCI CTO without any remaining lesion at least 30% proximal to the stented segment.
3) Possibility to perform physiologic measurements and OCT (optical coherence tomography) of sufficient quality.
4) Patients willing and capable to provide written informed consent.

Exclusion criteria

1) Contra-indication for adenosine.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-08-2021
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-05-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-01-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT04780971
CCMO	NL76172.075.21