COMPLEX LARGE-BORE RADIAL PCI TRIAL

Published: 11-02-2019
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Primary objectiveTo investigate if TR PCI is associated with less access site related bleeding and/or vascular complications as compared with TF PCI for complex coronary lesions with large-bore 7 Fr. guiding catheters.Secondary objectives: To...

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

Summary

ID

NL-OMON48821

Source
ToetsingOnline

Brief title
COLOR Trial

Condition

- Coronary artery disorders

Synonym
atherosclerosis, complex coronary lesion

Research involving
Human

Sponsors and support

Primary sponsor: Maatschap cardiologie, Zwolle
Source(s) of monetary or material Support: Maatschap Cardiologie Isala,Terumo

Intervention

Keyword: complex coronary lesions, percutaneous coronary intervention, Transradial Intervention

Outcome measures

Primary outcome

The primary endpoint is defined as BARC type 2, 3 or 5 bleeding or vascular complication related to the randomized access site (during hospitalization).

Secondary outcome

The secondary endpoints are defined as:

1) Non-access site related BARC type 2, 3 or 5 bleeding and/or vascular complications (hospitalization)

2) MACE (hospitalization and 1-month)

3) Procedural success, procedural time, fluoroscopy time, contrast use and crossover rate

Study description

Background summary

The radial artery has become the standard access site for percutaneous coronary interventions (PCI). This is driven by the lower rate of major bleeding and vascular complications, particularly in patients with acute coronary syndromes (ACS) treated with more intensive antithrombotic therapy. The lower mortality rate in ST-elevation myocardial infarction (STEMI) has led to a strong recommendation in current guidelines for TR intervention.
A patient group that may also benefit from TR intervention are patients with complex coronary lesions requiring treatment with large-bore guiding catheters (>= 7 fr). Large-bore guiding catheters provide better back-up and materials* compatibility, leading to better procedural success rates in more complex lesions. In most instances, the femoral artery is used for complex PCI with large-bore guiding catheters due to the radial artery - sheath mismatch which is in return associated with vascular bleeding complications and adverse clinical outcome.
With the introduction of the 7 Fr. thin-wall TR introducer sheath (Glidesheath Slender®, Terumo), TR complex PCI may still be performed in the majority of patients with standard large-bore guiding catheters. The outside diameter is reduced by 1 Fr while maintaining the inner-diameter equivalent. It was

recently shown that complex PCI with a 7 Fr Glidesheath Slender is safe and effective.

Study objective

Primary objective
To investigate if TR PCI is associated with less access site related bleeding and/or vascular complications as compared with TF PCI for complex coronary lesions with large-bore 7 Fr. guiding catheters.

Secondary objectives: To compare the TR and TF approach with regard to procedural success, procedural time, fluoroscopy time, contrast use, crossover and MACE rates for complex PCI with large-bore 7 Fr. guiding catheters.

Exploratory objectives:
Upper and lower extremity dysfunction (TR vs TF access)
Pain (VAS)(TR vs TF access)

Study design

international, multicentre, randomized study

Intervention

patients will be randomized to:
- complex PCI with 7Fr catheter via the artery radialis
or
- complex PCI with 7Fr catheter via the artery femoralis

Study burden and risks

The feasibility and safety of complex PCI with a 7 Fr Glidesheath Slender has been previously confirmed11. All participating centers have large experience with complex PCI through the radial and femoral artery. PCI and medical treatment are performed according to the local standards and current international guidelines. Patients will not be exposed to extra visits. The clinical status and patient reported outcomes will be gathered by a phone call at 1-month follow-up. Blood collection during hospitalization will be part of standard care. Based on the available data we consider the risks and burden of this research project to be small. With minimal effort and risk, patients included in this study are able to contribute to research to that may improve the treatment of complex coronary lesions with large bore-guiding catheters, which may have large impact on clinical practice and guidelines. This study will be conducted in full accordance with the principles of the Declaration of Helsinki.

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

1) Use of 7 Fr guiding catheter is indicated for complex PCI, according to the expertise of the treating
physician.
2) Age 18 years or older

Exclusion criteria

1) Inability to obtain informed consent
2) contra-indication for radial or femoral access
3) Cardiogenic shock

4) ST elevation myocardial infarction

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2019
Enrollment:	236
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2019
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-09-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL66831.075.18