ULTRASOUND GUIDED TRANSFEMORAL COMPLEX LARGE-BORE PCI TRIAL

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To investigate if ultrasound guided femoral access is associated with less clinically relevant access site related bleeding and/or vascular complications requiring intervention as compared to the fluoroscopy guided method for complex PCI with large-...

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

Summary

ID

NL-OMON51199

Source
ToetsingOnline

Brief title
ULTRACOLOR Trial

Condition

- Coronary artery disorders

Synonym
atherosclerosis, complex coronary lesion

Research involving
Human

Sponsors and support

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

Intervention

Keyword: complex coronary lesions, percutaneous coronary intervention, transfemoral intervention, ultrasound

Outcome measures

Primary outcome

To investigate if ultrasound guided primary femoral access is associated with

less clinically relevant access site related bleeding (BARC 2,3 or 5) and/or

vascular complication requiring intervention as compared to fluoroscopy guided

cannulation for complex PCI with large-bore access.

Secondary outcome

To compare ultrasound guided with fluoroscopy guided femoral access for complex

PCI with large-bore access with regard to the following objectives (definitions

in appendix I):

- BARC 2, 3 or 5 access-site related bleeding or vascular complication of

secondary access site (femoral or radial, defined in appendix I)

- MACE

- Procedural duration

- First pass puncture

- Accidental venous puncture

- Vascular complication not requiring intervention

- Vascular closure device failure

Study description

Background summary

Although the transradial access site is nowadays predominantly used for the vast majority of coronary procedures, transfemoral access is used in a considerable proportion of complex percutaneous coronary intervention (PCI) when large bore guiding catheters are mandated. Especially in case of contra-indication for large bore radial access or the need for dual arterial access (hybrid PCI of chronic total occlusion (CTO)), large bore transfemoral access is frequently used. However, bleeding and vascular complications are strongly associated with femoral access, especially when large bore cannulation is used. The application of ultrasound guidance for large bore femoral access might reduce the occurrence of clinically relevant bleeding and vascular complications.

Study objective

To investigate if ultrasound guided femoral access is associated with less clinically relevant access site related bleeding and/or vascular complications requiring intervention as compared to the fluoroscopy guided method for complex PCI with large-bore access.

Study design

ULTRACOLOR is a prospective, multicentre, randomized investigator-initiated trial designed to enroll 542 subjects with an indication for PCI for complex coronary lesions. See definition of complex coronary lesions in appendix I. Subjects will be randomized in a 1:1 fashion to either ultrasound guided femoral access or fluoroscopy guided femoral access. A clinical follow-up is scheduled at 1 month after index procedure.

Intervention

Ultrasound guided femoral access versus fluoroscopy guided femoral access.

Study burden and risks

Ultrasound guided puncture introduces no additional risks compared to standard practice. All participating sites have large experience with complex PCI and ultrasound or fluoroscopy guided femoral access. PCI and medical treatment are performed according to the local standards and current international guidelines. Subjects will not be exposed to extra visits. The clinical status and subject 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 the risks and burden of this research project are considered 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 complex coronary lesions with large bore-guiding catheters, which may have

large impact on clinical practice and guidelines.

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 the femoral artery for primary or secondary access with >= 7 Fr guiding catheter as indication 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 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:	Recruiting
Start date (anticipated):	09-06-2021
Enrollment:	380
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2021
Application type:	First submission
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	NL75441.075.21
Other	registratienummer volgt z.s.m.