IMPROVE Handstudie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19902

Source
NTR

Brief title
IMPROVE

Health condition

Percutaneous coronary intervention
Upper extremity dysfunction
Slender PCI
Radial artery

Sponsors and support

Primary sponsor: Investigator initiated:dr. A.J.J. IJsselmuiden, Interventional Cardiologist
Source(s) of monetary or material Support: Svelte Medical Systems

Intervention

Outcome measures

Primary outcome

The main study parameter is a binary score of upper extremity dysfunction after two weeks as compared to baseline. A positive score is defined as 1 point increase in at least two of the following scores, measured individual for both sides, two weeks after TR-PCI:
. At least 2 points increase in Numeric Rating Scale for pain with regard to the upper

extremity.
. Absent signal when evaluating the radial artery using Doppler ultrasound.
. Strength:
At least 20% decrease in palmar grip strength compared to baseline.
At least 20% decrease in pinch grip strength compared to baseline.
. At least two filaments decrease in sensibility of the hand using Semmes-Weinstein filaments according to WEST.
. At least 7% increase of the circumference of the hand, using the Figure of eight-method.
. At least 7% increase of the circumference of the forearm, measured at 8 centimetres distally from the medial epicondyle.

Secondary outcome

• A binary score of upper extremity dysfunction after one and six months as compared to baseline.
• Cardiac related secondary endpoints
o Successful arterial access of the target radial artery, defined as the ability to successfully advance a guiding catheter and position it in the coronary ostium
o Percentage of cross-over from radial to femoral acces
o Presence of branching anomaly (high radial artery take-off), tortuosity (none, mild, moderate or severe), stenosis (not encountered or percentage of stenosis encountered) and/or spasm (none, mild, moderate or severe) of the radial artery
o Access-route complications, dissection or perforation of radial, brachial or subclavian artery, as evidenced by angiography or computed tomography
o Procedural success (defined as <30% residual stenosis at the end of the procedure)
o Procedural time (time from sheet insertion to haemostatic device)
o Stent time (time to stent insertion to angiographic success)
o Material consumption (e.g. balloons, stents, wires)
o Medication regimen (e.g. Heparin, DAPT, anticoagulation, ACT)
o Catheter performance
o Major adverse cardiac and cerebrovascular events (MACCE) at procedure, MACCE defined as: Myocardial infarction (MI) according to the Third Universal definition of Myocardial Infarction, Target vessel revascularisation, either by PCI or surgical, death, Cerebrovascular accident (CVA)
o Bleeding events (according to Academic Research Consortium definitions) at procedure and at each consecutive follow-up
o MACCE as defined above at each consecutive follow-up

• Upper extremity related secondary endpoints
o Vessel anomalies, dissection and occlusion objectified with peri-procedural upper extremity angiography (subgroup)
o Radial artery occlusion defined as absent signal when evaluating the radial artery using Doppler ultrasound examination, and optionally limiting flow with Allen’s test
o In case of radial artery occlusion: location with respect to the prescribed landmark, i.e. the crossing of the radial artery over the radiocarpal joint, and dimensions of the thrombus, objectified by ultrasound of the upper extremity.
o Access –site Hematoma’s (minor (<5 cm) and major (>5 cm))

o NPRS-score with regard to the upper extremity at within 24 hours, two weeks, one and six months.
o To determine if change in the Boston Carpal Tunnel Questionnaire (BCTQ) score is associated with catheter size
o Presence or absence of arterial pulse when evaluating the radial artery using Doppler ultrasound examination extremity at within 24 hours, two weeks, one and six months.
o AROM goniometry values in degrees of the upper extremity at two weeks, one and six months.
o Strength in Newton at two weeks, one and six months:
Palmar grip strength
Key grip strength
o Sensibility of the hand using Semmes-Weinstein filaments according to WEST at two weeks, one and six months.
o Circumference of the hand in centimetres using the Figure of eight-method extremity at one day, two weeks, one and six months.
o Circumference of the forearm in centimetres at within 24 hours, two weeks, one and six months.
o If the subject is referred to the hand surgeon:
Diagnostic procedures performed by the surgeon
Diagnosis of the hand surgeon
Administered/Applied treatment

Study description

Background summary

Transradial percutaneous coronary intervention (TRPCI) is rapidly becoming the gold standard especially in primary percutaneous coronary intervention (PCI). Recent interim results of the ARCUS trial (Effects of trAnsRadial perCUtaneouS Coronary Intervention on Upper Extremity Function) showed upper extremity dysfunction (UED) after TRPCI.

This study will compare UED following slender TRPCI using small bore catheters (5F) compared to standard TRPCI using regular size guiding catheters (6F) and conventional stent techniques on two-weeks, one month and 6-months clinical outcomes from the multicenter IMPROVE trial

This trial will be performed in six Dutch hospitals with extensive experience in slender TRPCI.

Study objective

The main objective of this study is to compare upper extremity dysfunction (UED) following slender TRPCI using small bore catheters (5F) compared to standard PCI using regular size guiding catheters (6F) and conventional stent techniques at two weeks of follow-up.

Study design

Baseline, 4-24 h after slender TRPCI and 2 weeks, 1 and 6 months after slender TRPCI.

Intervention

Intervention:
Slender TRPCI using 5F guiding catheters and patent hemostasis of the radial artery.

(Historical) Control intervention:
340 patients treated with standard radial PCI using 6F sheaths and 6F guiding catheters, and conventional stent techniques, following non-oxygen saturation guided hemostasis.

Contacts

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Eligibility criteria

Inclusion criteria

- Presenting for elective slender TRPCI using 5F catheters and slender PCI at one of the study centres.
- The radial artery can be palpated, and Doppler ultrasound examination of the radial artery shows non-occlusive flow.

Exclusion criteria

- Currently enrolled in another study that clinically interferes with the current study and that

has not passed the
primary endpoint.
- The clinical condition prohibits or hinders informed consent and/or baseline examinations. E.g. cardiogenic
shock and cardiopulmonary resuscitation or subconscious and semiconscious state.
- Co-morbid condition(s) that could limit the subject's ability to participate in the study or to comply with follow-up
requirements, or impact the scientíIic integrity of the study, e.g. loss of voluntary motor control of the studied
extremities.
- Previous attempts of TRA (transradial approach) were unsuccessful.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-11-2018
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-07-2018
Application type:	First submission

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
NTR-new	NL7189
NTR-old	NTR7380
Other	NCT number : 220119966573888

Study results