A cohort study evaluating upper extremity function after slender transradial percutaneous coronary intervention

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

Summary

ID

NL-OMON50481

Source
ToetsingOnline

Brief title
Upper extremity dysfunction post slender radial PCI

Condition

- Coronary artery disorders
- Peripheral neuropathies
- Embolism and thrombosis

Synonym
complaints of hand, upper extremity dysfunction, wrist and arm

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Sponsor (Svelte)

Intervention

Keyword: percutaneous coronary intervention, radial artery, Slender PCI, upper extremity dysfunction

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 at least two

of the following scores, two weeks after TR-PCI, measured individual for both

sides:

* *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:

o *20% decrease in palmar grip strength compared to baseline.

o *20% decrease in pinch grip strength compared to baseline.

* At least 2 filaments decrease in sensibility of the hand using

Semmes-Weinstein filaments according to WEST.

* *7% increase of the circumference of the hand, using the Figure of

eight-method.

* *7% increase at of the circumference of the forearm, measured at 8

centimetres distally from the medial epicondyle.2

Secondary outcome

Secondary endpoints can be divided in cardiac and upper extremity related endpoints:

* Cardiac related secondary endpoints

- 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.
- Percentage cross-overs van arteria radialis naar arteria femoralis en het percentage cross-overs van een 5F procedure naar 6F procedure.
- 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
- Access-route complications, dissection or perforation of radial, brachial or subclavian artery, as evidenced by angiography or computed tomography
- Procedural success (defined as <30% residual stenosis at the end of the procedure)
- Procedural time (time from sheet insertion to haemostatic device)
- Stent time (time to stent insertion to angiographic success)
- Material consumption (e.g. balloons, stents, wires)
- Medication regimen (e.g. Heparin, DAPT, anticoagulation, ACT)
- Catheter performance
- 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)

- Bleeding events (according to Academic Research Consortium definitions) at procedure and at each consecutive follow-up

- MACCE as defined above at each consecutive follow-up

* Upper extremity related secondary endpoints

- Arthrosis, objectified with an pre-procedural X-ray of the upper extremity (subgroup)

- Vessel anomalies, dissection and occlusion objectified with peri-procedural upper extremity angiography (subgroup)

- Radial artery occlusion defined as absent signal when evaluating the radial artery using Doppler ultrasound examination, and optionally limiting flow with Allen*s test.

- 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.

- Access *site Hematoma*s (minor (<5 cm) and major (*5 cm))

- NPRS-score with regard to the upper extremity at within 24 hours, two weeks,

one and six months.

-To determine if change in the Boston Carpal Tunnel Questionnaire (BCTQ) score is associated with catheter size, measured individually for both sides at two weeks, one and six months.

- 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.

- AROM goniometry values in degrees of the upper extremity at two weeks, one and six months.

- Strength in Newton at two weeks, one and six months:

* Palmar grip strength

* Key grip strength

- Sensibility of the hand using Semmes-Weinstein filaments according to WEST at two weeks, one and six months.

- Circumference of the hand in centimetres using the Figure of eight-method extremity at one day, two weeks, one and six months.

- Circumference of the forearm in centimetres at within 24 hours, two weeks, one and six months.

- 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

The Transradial Approach (TRA) is increasingly popular as a default technique for angioplasty due to a significant reduction in procedural complications and access-site complications, resulting in significantly decreased mortality in STEMI patients, shorter hospital stays, increased patient satisfaction and lower associated costs. However, the exact effects of TRA procedures on upper extremity function are unknown. Interim results of the ongoing ARCUS trial showed 62.8% of subjects had manifestations of upper extremity dysfunction (UED) on the side of the intervention at two weeks follow-up. Referral to a hand surgeon was necessary in 8 patients (6.6%). Radial artery occlusion (RAO) was reported in 10% of patients. Patients with UED were significantly more likely to have RAO than those without (9.8% vs. 0%; P<0.001). Regardless of the elastic properties of the radial artery, the outer diameter of the sheath should be, whenever possible, smaller than the radial artery during TRA. Ensuring a sheath-to-artery ratio <1 is an essential factor in preventing RAO. Therefore, slender sheaths should be used for diagnostic angiography and for many non-complex coronary interventions.

Recently, Dharma et al. found that duration of compression alone was a strong predictor of RAO, reinforcing the hypothesis of minimizing radial injury by reducing compression time.
Additionally, achieving patent haemostasis after the procedure results in a vastly decrease in RAO rates. Due to the increased popularity of TR-PCI and its suggested association with UED, this study proposal aims to provide more insight in areas of improvements regarding prevention of RAO and other access-route complications causing UED, the risk factors for developing these complications and the influence of TRA on upper extremity function after TR-PCI whilst using the latest technology available in guiding catheters (e.g. hydrophilic coatings, 5F catheters, and slender PCI). Furthermore, we want to assess the effect of the radial approach type and minimized compression time in combination with patent haemostasis on RAO and UED.

Study objective

The main objective of this study is to compare upper extremity dysfunction following slender TRPCI using small bore catheters (*5F) compared to standard PCI using regular size guiding catheters(*6F) and conventional stent techniques. Secondary objectives are to minimize radial artery occlusions, to provide insight in the consequences for functional status, influencing factors and financial costs of this morbidity, and to generate hypotheses for further clinical research into this matter.

Study design

Non-blinded, multicenter controlled prospective cohort study with 100 subjects and a historical control group consisting of 500 subjects (ARCUS trial). The primary endpoint will be determined at two weeks post-procedure and a total follow-up duration of six months is planned.

Study burden and risks

- Time consumption, completion of questionnaires, additional physical examination and Doppler ultrasound of the radial artery.
- Benefit of early detection of possible complications due to intensive follow-up.

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

- Presenting for elective slender TRPCI using *5F catheters and a stent on the wire or RX DES Stent 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 scientific 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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2018
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Guiding catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-09-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-04-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	220119966573888
CCMO	NL65738.101.18