A cohort study evaluating upper extremity dysfunction after percutaneous coronary intervention using the radial artery as access route

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

Summary

ID

NL-OMON38780

Source
ToetsingOnline

Brief title
Upper extremity dysfunction post radial PCI

Condition

- Coronary artery disorders
- Joint disorders
- Peripheral neuropathies

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

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: onafhankelijke grant Albert Schweitzerziekenhuis en bijdrage maatschap cardiologie en plastische chirurgie

Intervention

Keyword: complications, percutaneous coronary intervention, radial artery, upper extremity dysfunction

Outcome measures

Primary outcome

To answer the main objective of this study the following composite endpoint

will be evaluated at two weeks:

• A binary score of upper extremity dysfunction. A positive score is defined as

the presence of at least a >=1 point increase in either the symptom-severity

score or the functional-status score of the Levine-Katz (Boston) questionnaire

or at least two of the following decreased scores two weeks after TR-PCI:

o >=15% decrease in the *Disabilities of the Arm, Shoulder and Hand* outcome

measure (DASH) compared to baseline.

o Increase in Visual Analogue Scale pain score (VAS) with regard to the upper

extremity of >=2 points compared to baseline.

o Absent signal when evaluating the radial artery using Doppler ultrasound

examination.

o >=10% decrease in active range of motion (AROM) goniometry of the upper

extremity compared to baseline with a minimum decrease of 10o.

o Strength

* >=60N decrease in palmar grip strength compared to baseline.

* >=12N decrease in pinch grip strength compared to baseline.

* >=15% decrease in isometric strength of the following maneuvers compared to baseline:

• Flexion and extension of the elbow.

• Flexion and extension of the wrist.

o At least one filament decrease in sensibility of the hand using Semmes-Weinstein filaments according to WEST compared to baseline.

o >=1cm increase at volumetry of the hand using the Figure of eight-method to baseline.

o >=1cm increase at volumetry of the forearm measured circumferentially 8cm distal of the medial epicondyle.

Secondary outcome

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

• Cardiac related secondary endpoints

o Successful arterial access of the target radial artery

o Percentage of cross-over from radial to femoral access

o Presence of angulation, tortuosity, stenosis or spasm

o Access route complications, dissection or perforation of radial, brachial or subclavian artery

o Procedural success (defined as <30% residual stenosis)

o Procedure time

o Radiation time and dose

o Major adverse cardiac events (MACE) at procedure.

o Bleeding events at procedure and at each follow-up

o MACE at each follow-up

• Upper extremity related secondary endpoints

o Symptom-severity score and the functional-status score of the Levine-Katz (Boston) questionnaire at two weeks, one and six months

o DASH outcome measure at two weeks, one and six months.

o VAS-score with regard to the upper extremity at one day, two weeks, one and six months.

o Presence or absence of arterial pulse when evaluating the radial artery using Doppler ultrasound examination extremity at one day, two weeks, one and six months.

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

o Strength at two weeks, one and six months:

* Palmar grip strength

* Pinch grip strength

* Isometric strength of the following maneuvers:

• Flexion and extension of the elbow

• Flexion and extension of the wrist

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

o Volumetry of the hand using the Figure of eight-method extremity at one day, two weeks, one and six months.

o Volumetry of the forearm at one day, two weeks, one and six months.

o If the primary endpoint has been reached:

* Diagnostic procedures

* Diagnosis

* Performed treatment

* Upper extremity related absence of work in days

Study description

Background summary

The radial artery as access for percutaneous coronary interventions (PCI) was first considered as such in 1992 by Kiemeneij et al and is rapidly becoming the gold standard especially in primary PCI during which multiple antithrombotic agents are used. The main rationale for this conversion from femoral access to radial access is the significantly decreased mortality when compared to the femoral route even considering the slightly increased learning curve.
However despite these positive findings regarding radial artery access several anecdotal or methodological poor articles exist in the literature regarding non-lethal complications. Such as endothelial denudation and hematomas, caused by spasm or perforation. These can result in extensive oedema or even compartment syndrome possibly resulting in permanent neurovascular damage of the upper extremity. Other described complications of TR-PCI are radial artery occlusion possibly resulting in hand ischemia, arterio venous fistula, pseudoaneurysms, chronic pain or CRPS. These less frequent but possibly debilitating complications are reported in very low incidences in larger studies or only in case reports. The possible subsequent dysfunction of the target upper extremity post TR-PCI has never been properly evaluated.
The proposed study has the intention to provide more insight in these access route complications, the risk factors for developing these complications and the influence of transradial access on upper extremity function after TR-PCI.
More research on these radial artery access route complications is necessary in creating a complete profile of complications of the increasingly popular and very successful transradial intervention especially focusing on upper extremity and hand function.

Study objective

The main objective of this study is to provide insight in the morbidity with regards to the upper extremity surrounding the radial access route in percutaneous coronary interventions.

Secondary objectives are the following:
• To provide insight at the consequences of this morbidity regarding functional status.
• To identify factors that influence the occurrence of upper extremity complications post TR-PCI.
• To identify subjects who might benefit from early referral to a dedicated *hand centre*.
• To provide insight at the financial consequences of these upper extremity complications both by increased health consumption as well as decreased labour productivity.
• To generate hypotheses for further clinical research with regard to upper extremity dysfunction after TR-PCI.

Study design

Single centre prospective cohort study without control group of 500 subjects. The primary endpoint is determined after two weeks and a total follow-up duration of six months is planned.

Study burden and risks

- Time consumption, completing questionnaires, aditional physicla examination en doppler ultrasound
- 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 TransRadial Percutaneous Coronary Intervention (TR-PCI) at the study centre.
-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 presenting condition prohibits or hinders informed consent and/or baseline examinations, such as a subconscious or semiconscious state, cardiogenic shock or cardiopulmonary resuscitation.
-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 studies extremities

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2014
Enrollment:	490
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	19-12-2013
Application type:	First submission
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

ID: 23742
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45613.101.13
Other	volgt

Register	ID
OMON	NL-OMON23742