Upper extremity dysfunction after dotter procedures via the wrist

No registrations found.

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

Summary

ID

NL-OMON23742

Source
Nationaal Trial Register

Brief title
ARCUS

Health condition

transradial percutaneous coronary interventions, upper extremity dysfunction

Sponsors and support

Primary sponsor: Carplast fund
Source(s) of monetary or material Support: Carplast fund

Intervention

Outcome measures

Primary outcome

The main study parameter is a binary score of upper extremity dysfunction after two weeks as compared to baseline.

Secondary outcome

The secondary study parameters will be divided in cardiac and upper extremity related endpoints and will be used to answer the secondary objectives.

Study description

Background summary

Transradial percutaneous coronary intervention is rapidly becoming the gold standard especially in primary PCI,with increased use of antithrombotic agents, where most benefit of the radial approach can be expected such as reduced major bleeding and mortality. However there is very limited research available looking at the consequences of transradial access for upper extremity function.
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 to provide insight in the consequences for functional status, factors influencing and financial costs of this morbidity, to identify subject who might benefit from early referral and treatment of this morbidity and to generate hypotheses for further clinical research into this matter.

Study objective

Approximately 20% of the patients will experience complications or upper extremity dysfunction after PCI

Study design

After intervention patients will undergo follow-up after 24 hours, two weeks, one and six months.

Intervention

All patients will, after baseline examinations be treated with the intent of using the radial artery for access.

Contacts

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Eligibility criteria

Inclusion criteria

• Presenting for 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 this 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.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-01-2014
Enrollment:	490
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38780
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4523
NTR-old	NTR4659
CCMO	NL45613.101.13
OMON	NL-OMON38780

Study results

Summary results

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