Upper extremity dysfunction after dotter procedures via the wrist

Gepubliceerd: 06-05-2014 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23742

Bron
Nationaal Trial Register

Verkorte titel
ARCUS

Aandoening

transradial percutaneous coronary interventions, upper extremity dysfunction

Ondersteuning

Primaire sponsor: Carplast fund
Overige ondersteuning: Carplast fund

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-01-2014
Aantal proefpersonen:	490
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38780
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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