# IMPROVE Handstudie

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

## Samenvatting

### ID

NL-OMON19902

**Bron**
NTR

**Verkorte titel**
IMPROVE

**Aandoening**

Percutaneous coronary intervention
Upper extremity dysfunction
Slender PCI
Radial artery

### Ondersteuning

**Primaire sponsor:** Investigator initiated:dr. A.J.J. IJsselmuiden, Interventional Cardiologist
**Overige ondersteuning:** Svelte Medical Systems

### 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. 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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 scientiĺic integrity of the study, e.g. loss of voluntary motor control of the studied
extremities.
- Previous attempts of TRA (transradial approach) were unsuccessful.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 26-11-2018 |
| Aantal proefpersonen: | 100 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 16-07-2018 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7189 |
| NTR-old | NTR7380 |
| Ander register | NCT number : 220119966573888 |

# Resultaten