# Ischemia (FFR) Driven Complete Revascularization versus Usual Care in Patients with Non-ST Elevation Myocardial Infarction and Multivessel Diseases.

# The South Limburg Myocardial Infarction Study Group

Gepubliceerd: 14-03-2018 Laatst bijgewerkt: 18-08-2022

Ischemia driven (FFR) complete percutaneous revascularisation of all significant stenosis in the non-culprit lesion performed within the index PCI procedure will improve clinical outcomes compared to the usual care, guided by discretion of the...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON23247

**Bron**
NTR

**Verkorte titel**
SLIM

**Aandoening**

coronary artery disease; NSTEMI; non ST-elevation myocardial infarction; multivessel disease; fractional flow reserve; FFR; culprit lesion; coronairlijden; non ST-elevatie myocardinfarct; meervatslijden

## Ondersteuning

**Primaire sponsor:** Zuyderland Medical Centre, Heerlen, The Netherlands
and
Maastricht University Medical Centre +, Maastricht, The Netherlands
**Overige ondersteuning:** Abott

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Primary study endpoints are defined as the incidence of MACE (Composite endpoint of all cause death, non-fatal Myocardial Infarction, any revascularisation and stroke) at 12 months.

# Toelichting onderzoek

### Doel van het onderzoek

Ischemia driven (FFR) complete percutaneous revascularisation of all significant stenosis in the non-culprit lesion performed within the index PCI procedure will improve clinical outcomes compared to the usual care, guided by discretion of the physician.

### Onderzoeksopzet

Time line

Initial enrolment May 2018

Last enrolment May 2020

One-year follow-up May 2019

Three year follow-up May 2023

Follow-up

For endpoint adjudication office-based direct visits will be performed at 1, 12 month and telephone-based interviews will be performed at 24 and 36 months.

### Onderzoeksproduct en/of interventie

Patients will be enrolled and randomised in a 1:1 fashion between the ischemia driven (FFR) revascularisation strategy, versus usual care, after completion of a successful culprit lesion PCI. All patients who present at least with one lesion with a stenosis of approximately 50% or more in a non-IRA with a diameter of ≥ 2.0 mm and fulfil the inclusion and exclusion criteria will be enrolled.

# Contactpersonen

## Publiek

Tobias Pustjens
[default]
The Netherlands

## Wetenschappelijk

Tobias Pustjens
[default]
The Netherlands

# Deelname eisen

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

• Patients aged between 18-85 years presenting with non-STEMI according to current guidelines, who will be treated with PCI of the culprit and have at least one stenosis of >50% in a non-IRA on QCA or visual estimation of baseline angiography and judged feasible for treatment with PCI by the operator.

• Non-IRA stenosis amenable for PCI treatment (operator’s decision)

• Signed informed consent

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

1. Left main disease (stenosis > 50%)

2. Chronic total occlusion of a non-IRA

3. Indication for or previous coronary artery bypass grafting

4. Uncertain culprit lesion

5. Complicated IRA treatment, e.g. extravasation, permanent no re-flow after IRA treatment (TIMI flow 0-1) and inability to implant a stent

6. Known severe cardiac valve dysfunction that will require surgery or TAVI in the follow-up period.

7. Killip class III or IV during the completion of culprit lesion treatment.

8. Life expectancy of < 1 year.

9. Intolerance to Aspirin, Clopidogrel, Plasugrel, Ticagrelor or Heparin.

10. Gastrointestinal or genitourinary bleeding within the prior 3 months.

11. Planned elective surgical procedure necessitating interruption of thienopyridines during the first 6 months post enrolment.

12. Patients who are actively participating in another drug or device investigational study, which have not completed the primary endpoint follow-up period.

13. Pregnancy

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland
Status: Werving nog niet gestart

| | |
|---|---|
| (Verwachte) startdatum: | 01-05-2018 |
| Aantal proefpersonen: | 414 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 14-03-2018 |
| 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 | NL6970 |
| NTR-old | NTR7158 |
| Ander register | : 17-T-142 |

# Resultaten