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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23247

Source
NTR

Brief title
SLIM

Health condition

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

Sponsors and support

Primary sponsor: Zuyderland Medical Centre, Heerlen, The Netherlands

and
Maastricht University Medical Centre +, Maastricht, The Netherlands
Source(s) of monetary or material Support: Abott

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

• Primary endpoint in subgroups at 12 and 24 months in the subgroup of patients.

• Composite endpoint of Net Adverse Clinical Events (NACE) defined as composite endpoint of Cardiac death, Myocardial Infarction, any Revascularisation, Stroke and major bleeding at 12, 24 and 36 months.

• Composite endpoint hospitalisation for heart failure and unstable angina pectoris at 12, 24 and 36 months.

• All-cause mortality or Myocardial infarction at 12, 24 and 36 months..

• Any revascularisation at 12, 24 and 36 months.

• Stent thrombosis at 12, 24 and 36 months.

• Bleeding (major and minor) at 48 hr and 12 months

• Primary endpoint at 36 months as well as outcomes of each component of the primary endpoint at 12 and 24 and 36 months.

• Left ventricular ejection fraction at 12 and 24 and 36 month (MIBI scan, MRI or Echocardiography)

Study description

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	414
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-03-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6970
NTR-old	NTR7158
Other	: 17-T-142

Study results