EXPLORE. Multi-center, randomized trial to study the impact of percutaneous coronary intervention on left ventricular function in patients with a non-infarct related chronic total occlusion after ST-elevation myocardial infarction: PCI vs. conservative approach in CTO patients after STEMI.

No registrations found.

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

Summary

ID

NL-OMON24093

Source
NTR

Brief title
EXPLORE

Health condition

1. ST-elevation myocardial infarction (STEMI);

2. percutaneous coronary intervention;

3. Chronic total occlusion;

4. left ventricular function;

NLD:

ST-elevatie myocard infarct (STEMI),

percutane coronaire interventie,

chronische totale occlusie,

linker ventrikel functie.

Sponsors and support

Primary sponsor: Investigator initiated study
Academic Medical Center ¨C University of Amsterdam
Department of cardiology
The Netherlands

Principal investigators:
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Source(s) of monetary or material Support: Research grant,
Abbott Vascular

Intervention

Outcome measures

Primary outcome

Measured by cardiac MRI at four months:

1. Left ventricular ejection fraction;

2. Left ventricular end-diastolic volume.

Secondary outcome

1. Left ventricular end-systolic volume measured by MRI at four months;

2. Left ventricular remodeling parameters, left ventricular mass, and infarct size measured by MRI at four months;

3. Angiographic analysis of the treated CTO at one year (in patients with PCI of the CTO);

4. Functional class according to the NYHA-Classification at 30 days, four months and one year;

5. Major Adverse Cardiac Event, defined as cardiac death, myocardial infarction, or coronary bypass grafting after four months and one, two, three, four and five years;

6. NT-proBNP at four months and at one year (relative to baseline);

7. Heart rate-adjusted QT duration measured by resting electrocardiography at four months and one year (relative to baseline).

Study description

Background summary

Multi-center, randomized, prospective two-arm trial in approximately 300 Patients with acute myocardial infarction treated with primary PCI and with a non-infarct related CTO. Patients are randomized to either PCI of the CTO or no CTO intervention after STEMI. Blinded evaluation of endpoints to determine whether PCI of the CTO within seven days after STEMI (versus no CTO intervention) results in a higher left ventricular ejection fraction and a lower left ventricular end-diastolic volume assessed by MRI at four months.

Study objective

An active revascularization strategy, i.e. recanalization of a CTO, might improve function in non-infarcted hibernating myocardium and promote infarct healing at the border zones. These effects may attenuate the remodeling process, which may lead to improved global LV function, decreased LVEDV, and improved survival.

Study design

1. Initial selection and informed consent;

2. Randomization: PCI of the CTO/No CTO intervention;

3. Hospital discharge;

4. 30 day follow-up;

5. 4 month follow-up;

6. 12 month follow-up;

7. 2 year follow-up;

8. 3 year follow-up;

9. 4 year follow-up;

10. 5 year follow-up.

Intervention

PCI of the non-infarct related CTO within seven days after primary PCI for STEMI versus no CTO intervention within one year after inclusion.

Contacts

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Eligibility criteria

Inclusion criteria

Patients after successful primary PCI for STEMI are screened for entry into this trial. A primary PCI is ¡®successful¡¯ when the residual stenosis of the culprit lesion < 50% and the TIMI flow ¡Ý 2.

Patients are suitable for inclusion in this trial if coronary angiography preceding the primary PCI reveals at least one chronic total occlusion with all of the following characteristics:

1. Located in a non-infarct related coronary artery:

a. In the left coronary system if the right coronary artery (RCA) is the culprit lesion;

b. In the RCA or left circumflex artery (LCX) if the left anterior descending artery (LAD) is culprit lesion;

c. In the RCA or LAD if the LCX is the culprit lesion;

2. A 100% luminal narrowing without antegrade flow or with antegrade or retrograde filling through collateral vessels;

3. Amenable to PCI treatment;

4. A reference diameter of ¡Ý 2.5 millimeters.

Exclusion criteria

1. Older than 80 years of age;

2. Persistent or permanent atrial fibrillation;

3. Known renal insufficiency (e.g. serum creatinine level of more than 265 ¦Ìmol/L (i.e. more than 3.5 mg/L));

4. More than 48 hours of hemodynamic instability after primary PCI, defined as pre-shock (heart rate >100/min. and or systolic blood pressure <100 mmHg) or shock (sustained systolic blood pressure ¡Ü 80 mmHg despite fluid hydration with ¡Ý two low dose or one high dose vasopressor or inotropic drug(s) or a cardiac index of ¡Ü 2.2 liters per minute per square meter of body-surface area and a pulmonary-capillary wedge pressure of at least 15 mmHg if known);

5. Cardiac events between primary PCI and randomization:

a. Extended myocardial infarction, as evidenced by a new episode of chest pain with new ST-segment elevations and a new CK / CK-MB peak;

b. Acute stent thrombosis;

c. Ventricular arrhythmias, i.e. sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) more than 48 hours after primary PCI (i.e. late ventricular arrhythmia);

6. Significant left main stenosis (diameter stenosis ¡Ý 50%);

7. Indication for Coronary Artery Bypass Grafting (CABG);

8. Severe valvular heart disease requiring cardiac surgery within four months;

9. Indication for implantable cardioverter defibrillator (ICD) within four months;

10. Inability to schedule the index procedure within seven days after primary PCI;

11. Unsatisfactory baseline investigations, i.e. MRI not suitable for endpoint assessment;

12. Any contraindication for MRI, i.e.:

a. pacemaker;

b. cerebrovascular clips;

c. claustrophobia;

13. Serious known concomitant disease with a life expectancy of less than one year;

14. Circumstances that prevent follow-up (no permanent home or address, transient, etc.);

15. Previous participation in this trial or any other trial within the previous 30 days.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2007

Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion Date:	30-10-2007
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	NL1075
NTR-old	NTR1108
Other	Explore : IA 107001.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A