Pressure-controlled Intermittent Coronary Sinus Occlusion in Patients with ST-segment Elevation Myocardial Infarction Treated by Primary Percutaneous Coronary Intervention: Safety and Feasibility Study

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Primary Objective:Proof of concept study designed to document the safety and feasibility of adjuvant treatment with the PICSO Impulse system in patients with acute anterior ST-segment elevation myocardial infarction (STEMI) treated with primary PCI...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON38279

Source
ToetsingOnline

Brief title
Prepare RAMSES

Condition

- Coronary artery disorders

Synonym
Acute myocardial infarction

Research involving

Human

Sponsors and support

Primary sponsor: Miracor Medical Systems GmbH
Source(s) of monetary or material Support: Miracor Medical Systems GmbH

Intervention

Keyword: Acute myocardial infarction, Microcirculation, Pressure-controlled intermittent coronary sinus occlusion, ST- elevation myocardial infarction

Outcome measures

Primary outcome

Assessment of the feasibility of PICSO in STEMI patients defined as the

successful delivery of the PICSO Impulse catheter and successful administration

of PICSO treatment for 90 minutes

Secondary outcome

Secondary Endpoints:

1. ST-segment time curve area for the first 3 hours on 24 hour continuous

12-lead ECG Holter monitor recording.

2. Occurrence of complete resolution of ST-segment elevation 30, 60, 90 and 120

minutes after last contrast injection prior to PICSO placement procedure on 24

hour continuous 12-lead ECG Holter monitor recording.

3. Microvascular perfusion assessed by MRI between 2-5 days post-primary PCI

procedure and at 120±14 days follow-up.

4. Infarct size assessed by MRI between 2-5 days after primary PCI and at

120±14 days follow-up.

5. Left ventricular function assessed by echocardiography between 2-5 days

after primary PCI and at 120±14 days follow-up.

Safety Endpoints:

1. Major adverse cardiac events (MACE)

2. Major adverse cardiac and cerebrovascular events (MACCE)

3. Net adverse clinical events (MACE + Bleeding)

4. (Severe) Adverse Device Event ((S)ADE) rates

Exploratory MRI endpoints:

1. Microvascular obstruction (in grams and percentage of total left ventricular mass and percentage of total infarct mass) assessed by MRI between 2-5 days post-primary PCI procedure and at 120±14 days follow-up.

2. Left ventricular ejection fraction (%), left ventricular end-diastolic volume (mL), and left ventricular end-systolic volume (mL) at 2-5 days and at 120±14 days.

3. Transmural extent of infarction (%).

Study description

Background summary

the presence of collateral flow in case of obstructive coronary artery disease or acute myocardial infarction has beneficial effects on morbidity and mortality. Pressure-controlled intermittent coronary sinus occlusion (PICSO) carries a promise of improving myocardial flow, decreasing microvascular obstruction and decreasing the rate of periprocedural and acute myocardial infarction without the increased risk of bleeding such as is encountered with GP2b3a inhibitors. We expect that PICSO is able to reduce infarct size in patients with acute myocardial infarction and thereby may improve long term outcome.

Study objective

Primary Objective:
Proof of concept study designed to document the safety and feasibility of adjuvant treatment with the PICSO Impulse system in patients with acute anterior ST-segment elevation myocardial infarction (STEMI) treated with primary PCI.

Secondary objective:
To assess the utility of different outcome measures of myocardial function following PICSO use in patients with acute anterior STEMI treated with primary PCI

Study design

A prospective multi-center study in which patients with an acute, left anterior descending artery (LAD) culprit ST-segment elevation myocardial infarction (STEMI) receive primary PCI (angioplasty followed by stent placement) and adjuvant 90 minutes PICSO treatment using the Miracor PICSO Impulse System

Intervention

All included patiénts will receive adjuvant PICSO treatment. This contains the insertion of the PICSO Impulse catheter through a femoral vein puncture en the administration of the PICSO treatment for 90 minutes.

Study burden and risks

Risk specifically introduced by the use of the PICSO Impulse system are bleeding complications in the groin due to the venous puncture necessary for introduction of the catheter as well as the presence of the catheter for approximately 90 minutes.
Possible complications are pulmonary emboli, and injury or chronic occlusion of the coronary sinus. These complications have, however, not been observed in previous clinical trials, and these are therefore considered to be rare.
The burden for a single patient consists of the PICSO treatment for 90 minutes. Apart from the treatment, patients are asked to return to the outpatient clinic of the AMC three times, with an additional MRI-scan and echocardiography during the 4-months follow up visit. A follow-up visit consists of history-taking, routine laboratory testing, electrocardiography and a physical examination. The follow-up visits last for approximately 30 minutes, the MRI-scan at four months follow up 90 minutes, the echocardiography at four months follow up 15 minutes . The total burden for the patient is 300 minutes during a 6 month period.

Contacts

Public
Miracor Medical Systems GmbH

Gumpendorfer Strasse 139 (top 1.05)
A-1060 Vienna
AT
Scientific
Miracor Medical Systems GmbH

Gumpendorfer Strasse 139 (top 1.05)
A-1060 Vienna
AT

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.First time anterior STEMI defined by the following:
a.Symptoms of myocardial ischemia > 30 minutes and < 12 hours.
b.ST-segment elevation > 1mm (> 0.1 mV) in two contiguous precordial leads in the anterior territory on a 12-lead ECG.
2.Uncomplicated PCI of a LAD culprit lesion
(defined as angioplasty followed by stent placement or direct stenting without the occurrence of an adverse event(s) that would preclude further study participation, such as major bleeding, perforation, hypotension, pulmonary edema or instability that in the judgement of the operator preclude participation in the trial)

Exclusion criteria

1.Younger than 18 years of age
2.Hospitalization with a primary diagnosis of acute myocardial infarction (AMI) previously or has evidence of previous Q-wave infarct
3.Left main coronary artery culprit lesion
4.Additional stenosis in the LAD for which PCI or CABG is likely to be needed in the next 6 months and which is not treated during the index procedure
5.Cardiogenic shock (systolic blood pressure *90 mmHg in spite of conservative measures) or pulmonary edema (O2 saturation <90% by pulse oximetry and the presence of rales or crackles)
6.Cardiac arrest requiring chest compression or resuscitation
7.Anatomical complications limit capacity to place PICSO Impulse device or achieve stable catheter placement or occlude coronary sinus
8.Known renal disease (GFR < 30 mL/min/1.73m2) or dialysis
9.History of stroke, TIA or reversible ischemic neurological disease within last 6 months
10.Left bundle branch block
11.Known contra-indication for magnetic resonance imaging (Metallic implant precluding MRI, claustrophobia, obesity precluding MRI, etc.)
12.Presence of any lead in the coronary sinus
13.Active or treated malignancies in the last 12 months
14.Previous coronary artery bypass graft surgery
15.Known severe anemia (Hgb < 10 g/dL or < 6.2 mmol/L)
16.Known platelet count < 100,000, known coagulopathy or bleeding diathesis, or unwilling to accept transfusions
17.Participation in another ongoing clinical study
18.Women of child-bearing age
19.Non-cardiac comorbidities and life expectancy < 1 year
20.Legal incompetence
21.A condition that, in the opinion of the Investigator, precludes participation, including compliance with all follow-up procedures

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2012
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Pressure-controlled Intermittent Coronary Sinus Occlusion (PICSO)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL37323.018.11