Bloodless Reperfusion in Acute Myocardial Infarction Pilot Study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON48480

Source
ToetsingOnline

Brief title
BRIAMI PS

Condition

- Coronary artery disorders

Synonym
Acute myocardial infarction, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute myocardial infarction, Bloodless reperfusion, Microvascular injury, No reflow

Outcome measures

Primary outcome

30-day major cardiac and cerebral events (MACCE), including peri-procedural complications

Time from start bloodless reperfusion technique (i.e. proximal balloon inflation) to PCI

Coronary wedge pressure (CWP) before saline infusion compared with CWP directly after saline infusion (prior to the actual opening of the infarct related artery), representing acute cardioprotection

Secondary outcome

* Pre- and post-reperfusion coronary wedge pressure (CWP) and its association with IS and MVO as measured with cMR

* Pre- and post-reperfusion coronary wedge pressure (CWP) and its association with left ventricular ejection fraction and volumes as measured with (2D and 3D) echocardiography

* Post-reperfusion index of microvascular resistance (iMR) and its association with cMR indices, electrocardiography (i.e. ST-segment recovery), and echocardiography

* Pre- and post-reperfusion CWP and iMR and their association with left ventricular end-diastolic pressure (LVEDP)

* Post-reperfusion fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) and their association with IS and MVO as measured with cMR

* Post-reperfusion FFR and iFR and their association with left ventricular ejection fraction and volumes as measured with (2D and 3D) echocardiography

* Post-reperfusion FFR and iFR and their association with cMR indices, electrocardiography (i.e. ST-segment recovery), and echocardiography

* Post-reperfusion FFR and iFR and their association with left ventricular end-diastolic pressure (LVEDP)

Study description

Background summary

Treatment of ST-elevation myocardial infarction (STEMI) by means of mechanically reperfusion is often accompanied by reperfusion injury. As pre- and postconditioning in STEMI appears to be ineffective, cardioprotection should occur parallel (perconditioning) to the sustained coronary occlusion and interact with the distal coronary arterial micro-circulation prior to epicardial restoration of flow. This is known as bloodless reperfusion and constitutes a new therapeutic strategy to tackle reperfusion injury.

Study objective

Primary objective is to assess the safety, feasibility and efficacy of the bloodless reperfusion technique in patients with STEMI. Secondly, we will collect pre- and post-reperfusion indices of microvascular (dys)function which may act as efficacy markers in future trials.

Study design

We will conduct a prospective, single-center registry in which the safety, feasibility and efficacy of the bloodless reperfusion technique will be studied. Furthermore, intracoronary measurements in the acute setting are collected and linked to infarct size (IS) and microvascular obstruction (MVO) as obtained by cardiac magnetic resonance (cMR).

Study burden and risks

Patients are subjected to state-of-the-art cardiac (interventional) care in concordance with international guidelines as applied to all STEMI patients. Additionally, Doppler flow / thermodilution measurements will be conducted

during primary PCI (pPCI). All materials and devices are routinely available at our catheterisation laboratory and are of low burden to the patients. Except from the bloodless reperfusion technique, all invasive methods and measurements are part of daily clinical care.
CMR is considered standard of post-STEMI care to evaluate the impact of the myocardial infarction on left ventricular function.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with an acute STEMI are eligible when they meet the following inclusion criteria: Symptom onset < 6 hours, Thrombolysis In Myocardial Infarction (TIMI) 0 flow, and at least 1 intermediate lesion in a non-infarct related artery. Patients need to be hemodynamically stable, responsive and

compos mentis.

Exclusion criteria

Major exclusion criteria are cardiogenic shock and a history of prior myocardial infarction or coronary artery bypass grafting (CABG).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-11-2019
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

ID: 20782
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68014.029.18
OMON	NL-OMON20782