Bloodless Reperfusion in Acute Myocardial Infarction

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20782

Source
NTR

Brief title
BRIAMI PS

Health condition

Acute Myocardial Infarction

Sponsors and support

Primary sponsor: Amsterdam University Medical Centers, location VUmc
Source(s) of monetary or material Support: Amsterdam University Medical Centers, location VUmc

Intervention

Outcome measures

Primary outcome

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

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)

Pre- and post-reperfusion CWP and iMR and their association with serum biomarkers (cardiac troponin, lactate)

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)

Post-reperfusion FFR and iFR and their association with serum biomarkers (cardiac troponin, lactate)

Study description

Background summary

Treatment of ST-elevation myocardial infarction (STEMI) by means of mechanically reperfusion has been shown to be of prognostic relevance. A downside of mechanically reperfusion is that it is often accompanied by reperfusion - or microvascular injury. Recently a promising technique to tackle reperfusion injury has been developed, bloodless reperfusion. In the current trial we will evaluate the safety and feasibility of this technique as well as evaluate intracoronary derived pressure parameters to identify microvascular injury prior to reperfusion in a STEMI population.

Study objective

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 in 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 design

The technique of bloodless reperfusion and measurement of CWP, IMR, iFR and FFR will be executed during the index procedure, the primairy PCI.

CMR will be performed at 2-7 days and 1 month follow-up

Intervention

The bloodless reperfusion technique will be evuluated:

A adequately sized semi-compliant balloon will be inflated at low pressure (2-4atm) proximal to the occlusion. Thereafter a double lumen microcatheter (over-the-wire) will be advanced distal to the occlusion. Coronary wedge pressure (CWP) will be measured with a pressure wire advanced through the microcatheter. Bloodless reperfusion can also be achieved through the micocatheter.

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Eligibility criteria

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.

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:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	0
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48480
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7379
NTR-old	NTR7587
CCMO	NL68014.029.18
OMON	NL-OMON48480

Study results