Microvascular Recovery in Acute MI, a multi center, prospective, randomized, single blind parallel-group comparison of sonothrombolysis versus standard of care performed after (post) coronary reperfusion (primary PCI).

Published: 02-08-2019
Last updated: 12-04-2024

To compare the relative efficacy of sonothrombolysis in the acute management of STEMI following primary percutaneous coronary intervention [PCI] in patients with persistent ST elevation compared with standard of care.

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

Summary

ID

NL-OMON52724

Source
ToetsingOnline

Brief title
MRUSMI

Condition

- Coronary artery disorders

Synonym
myocardial infarction and microcirculation

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Donatie Howard Foundation aan VUmc

Intervention

Keyword: acute myocadial infarction, microvascular obstruction

Outcome measures

Primary outcome

Som of ST-segment elevation after 60 min post initiation of Study Protocol

Secondary outcome

- Partial (>50%) and complete (>=70%) ST-segment resolution.

- Size of the infarct as measured by late gadolinium enhancement (LGE) on

cardiac magnetic resonance imaging (CMR) assessed on day 3-7 days and 4-6

months after infarction (on patients who can have a CMR)

- Left ventricular remodelling as assessed by contrast enhanced

echocardiography.

- The composite of all-cause death, cardiogenic shock, need for

defibrillator placement, or congestive heart failure (CHF) through day 180

Study description

Background summary

Rationale: The optimal treatment strategy in patients with acute ST-elevated myocardial infarction (STEMI) is immediate restoration of epicardial coronary blood flow. Thrombolytic therapy is the most widely used therapy, however, important limitations are a relatively low recanalization rate, and hemorrhagic

complications. Currently, primary percutaneous coronary intervention (PCI) is the treatment of choice in STEMI patients, however, its widespread use is hampered by limited availability of specialized facilities and trained staff. Also, peripheral microvascular obstruction often occurs, as part of the microvascular injury pathway. Additional drugs can be administered in this case, but detection of this obstruction is difficult, even with intracoronary measurements using specialized wires. A method by which this microvascular obstruction might be visualized is with ultrasound echocardiography and ultrasound contrast agents (UCAs). Luminity ®, an UCA, is recently re-introduced in Europe and is used to diagnostically image the myocardium even during PCI to visualize myocardial perfusion and indirectly obtain information on the amount of microvascular obstruction. This can enhance additional therapy given immediately after PCI and might reduce over-medication in patients. We hypothesize that UCA administration with Luminity ® with continuous ultrasound directly after PCI can be safely used to visualize the myocardial perfusion in the setting of acute ST-elevation myocardial infarction in patients premedicated with prasugrel or ticagrelor, aspirin and heparin.
Additionally, the application of ultrasound, and ultrasound in combination with thrombolytic agents have been investigated and were found to enhance thrombus dissolution in vitro and in vivo. Pilot studies demonstrated that ultrasound and microbubbles might have a beneficial effect on the microcirculation in humans.

Study objective

To compare the relative efficacy of sonothrombolysis in the acute management of STEMI following primary percutaneous coronary intervention [PCI] in patients with persistent ST elevation compared with standard of care.

Study design

The Microvascular Recovery in Acute MI will be a multi center, prospective, randomized, single blind parallel-group comparison of sonothrombolysis versus standard of care performed after (post) coronary reperfusion (primary PCI).

Intervention

MRUSMI
Sonothrombolysis: Intermittent diagnostic high mechanical index (MI) at 1.1 MI using an iE33 to the myocardium during an intravenous Luminity®, post PCI for 30 minutes
Control : Standard of care

Study burden and risks

Use of ultrasound contrast agent with very small risk of allergic reaction.

The study will be performed in a safe environment on the coronary care unit (and in the case of Ambulance sub study in the ambulance). Instable patients (cardiogenic shock etc.) will be excluded

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 presenting with STEMI within 12 hours of symptom onset and persisting ST-elevation on the ECG after PCI >=30% in the lead with the highest elevation compared to baseline ECG
Age >=30 years.
Adequate images with echocardiography

Exclusion criteria

1. Previous coronary bypass surgery
2. Cardiogenic shock
3. Known or suspected hypersensitivity to ultrasound contrast agent used for the study
4. Known bleeding diathesis or contraindication to glycoprotein 2b/3a inhibitors, anticoagulants, or aspirin
6. Known large right to left intracardiac shunts

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2019
Enrollment:	66
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound probe and machine
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Luminity/Definity
Generic name:	perflutren-containing lipid microspheres
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	02-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-01-2022

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2022
Application type:	Amendment
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
EudraCT	EUCTR2018-001277-24-NL
CCMO	NL65120.029.18