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Ultrasound contrast agents to facilitate sonothrombolysis in patients with acute myocardial infarction

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 20/08/2021	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Ultrasound contrast agents to facilitate sonothrombolysis in patients with acute myocardial infarction

Acronym
ULYSIS

Study objectives
The optimal treatment strategy in patients with Acute Myocardial Infarction (AMI) is immediate restoration of coronary blood flow. Although thrombolytic therapy is the most widely used therapy, Percutaneous Coronary Intervention (PCI) is the treatment of choice in AMI patients, however, its widespread use is hampered by limited availability of specialised facilities and trained staff. There is a need for simpler and low-risk methods for effective recanalisation of thrombosed arteries that can be initiated early in the disease process.

Recently, the application of ultrasound in combination with thrombolytic agents was found to enhance thrombus dissolution in vitro and in vivo. In vivo studies using thrombo-occlusive canine and rabbit models demonstrated that Ultrasound Contrast Agents (UCAs) enhance this thrombus dissolving effect of ultrasound, resulting in higher recanalisation rates of occluded arteries.

Hypothesis:
Under influence of ultrasound, UCAs enhance dissolution of thrombus in patients with acute ST-elevation myocardial infarction premedicated with aspirin and clopidogrel.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, placebo controlled, parallel group, single blinded multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute myocardial infarction

Interventions
After having received 150 - 325 mg aspirin and a loading dose of 300 mg clopidogrel, patients will be randomised to:
1. Ultrasound application with infusion of an ultrasound contrast agent, or
2. Control (infusion of saline without ultrasound application).

Immediately after ultrasound application, catheterisation will be performed.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aspirin and clopidogrel

Primary outcome(s)
Comparison of the UCA-group and the control group with respect to:
1. Patency of the culprit coronary artery
2. Thrombolysis In Myocardial Infarction (TIMI)-flow
3. Corrected TIMI frame count
4. Myocardial blush grade

Key secondary outcome(s))
1. ST-segment resolution
2. Release of cardiac enzymes
3. Echocardiographic wall motion score index
4. Safety

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Age 18 to 80 years
2. Diagnosed with acute myocardial infarction according to the criteria of the American College of Cardiology
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Previous myocardial infarction
2. Clinical instability

3. Pregnancy/breast feeding
4. Known pulmonary hypertension
5. Known allergy to Optison
6. Any reason judged by the investigators to hamper inclusion

Date of first enrolment
01/10/2005

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (The Netherlands)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2012	20/08/2021	Yes	No
Protocol article		08/03/2011	20/08/2021	Yes	No