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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON29439

**Source**
Nationaal Trial Register

**Brief title**
ULYSIS

**Health condition**

Patients with acute myocardial infarction

### Sponsors and support

**Primary sponsor:** VU University Medical Center
**Source(s) of monetary or material Support:** None

### Intervention

### Outcome measures

**Primary outcome**

Comparison of the UCA-group and the control group with respect to patency of the culprit coronary artery,
TIMI-flow,

corrected TIMI frame count,
myocardial blush grade.

**Secondary outcome**

1. ST-segment resolution;

2. Release of cardiac enzymes;

3. Echocardiographic wall motion score index;

4. Safety.

# Study description

**Background summary**

**Study title:**
Ultrasound contrast agents to facilitate sonothrombolysis in patients with acute myocardial infarction.'

**Background :**
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 specialized facilities and trained staff. There is a need for simpler and low-risk methods for effective recanalization 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 recanalization rates of occluded arteries.

**Objectives:**
To investigate whether application of ultrasound in combination with UCAs has a beneficial effect on obtaining coronary reperfusion and infarct size in patients with acute myocardial infarction pretreated with aspirin, heparin and a single bolus rt-PA**Design:**
A multi-center, randomized, placebo-controlled trial.

**Methods:**
The study population consists of 60 patients with acute myocardial infarction, referred for primary PTCA. After the inclusion criteria have been met, informed consent will be obtained. Patients receive a loading dose aspirin 500 mg, Heparin 5000 IU and a single bolus rt-PA 50 mg, and will be randomized to 1) ultrasound application with an continuous infusion of Luminity or 2) control. Ultrasound will be applied during 15 minutes, during continuous intravenous infusion of Luminity. After ultrasound application, patients will undergo catheterisation with standardized injection for assessment of patency of the culprit artery, myocarial blush grade, measurement of TIMI-frame count, and eventually PTCA. A continuous ECG-registration is made. Cardiac enzymes are measured at fixed time points during hospital stay. For follow-up, resting echocardiography and MRI are performed.

**End points:**
Efficacy of enhancement of sonothrombolysis with UCAs will be assessed by
1) comparing the UCA-group and the control group with respect to patency of the culprit coronary artery, TIMI-flow, corrected TIMI frame count, myocardial blush grade, and
2) ST-segment resolution, release of cardiac enzymes, global and segmental wall motion assessed by echocardiography and MRI
3) safety.

### Study objective

Under influence of ultrasound, ultrasound contrast agents enhance dissolution of thrombus in patients with acute ST-elevation myocardial infarction premedicated with aspirin, heparin and a single bolus rt-PA.

### Intervention

After having received a loading dose aspirin 500 mg, Heparin 5000 IU and a single bolus rt-PA 50 mg, patients will be randomized to
1. Ultrasound application with infusion of an ultrasound contrast agent, or
2. Control (infusion of saline without ultrasound application).
Immediately after ultrasound application, catheterization will be performed.

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Age 18-80 years;

2. Diagnosed with acute myocardial infarction according to the criteria of the American College of Cardiology;

3. Iinformed consent.

## Exclusion criteria

1. Previous myocardial infarction;

2. Clinical instability;

3. Pregnancy / breast feeding;

4. Known pulmonary hypertension;

5. Known allergy to Luminity ;

6. Any reason judged by the investigators to hamper inclusion.

# Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2007 |
| Enrollment: | 60 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 30-08-2005 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL127 |

| Register | ID |
| --- | --- |
| NTR-old | NTR161 |
| Other | : N/A |
| ISRCTN | ISRCTN32486185 |

# Study results

**Summary results**
N/A