# Timing of revascularisation in patients with transient ST segment elevation myocardial infarction

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We hypothesis that a immediate invasive strategy is superior to an delayed invasive strategy in patients with a transient ST segment elevation myocardial infarction.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27736

**Bron**
Nationaal Trial Register

**Verkorte titel**
TRANSIENT

**Aandoening**

STEMI
NSTEMI
Coronary angiography
Revascularisation
PCI
Transient ST segment elevation myocardial infarction.
Timing

### Ondersteuning

**Primaire sponsor:** initiator
**Overige ondersteuning:** initiator

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The primary end point of the study is total infarct size as percentage of the left ventricle at baseline CMR scan, performed 4 days after the start of symptoms

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: Patients presenting with ST-elevation myocardial infarction (STEMI), whose symptoms and electrocardiographic changes completely resolve upon admission and before the administration of reperfusion therapy, pose a therapeutic dilemma. The optimal management of this syndrome, termed as transient STEMI (TSTEMI), has not yet been fully established.
Objective: This study will investigate the optimal timing of coronary angiography and subsequent revascularisation in patients presenting with transient ST elevation myocardial infarction. Comparing coronary angiography and revascularisation immediately or pending on the GRACE score (>140, within 24 hours or <140, within 72 hours)

Study design: The study is a prospective, randomized controlled, multi-centre study.

Study population: The research population will be recruited from the general patient population presenting through LifeNet with ST-segment elevation, and complete normalization of ST-segment elevations on admission at the coronary care unit of the hospital with PCI facilities. A total of 141 consecutive patients will be included.

Intervention (if applicable): The patients will be randomized to either the immediate or delayed coronary angiography and subsequent revascularisation group.
Main study parameters/endpoints: The primary end point of the study is total infarct size as percentage of the left ventricle at baseline CMR scan, performed 4 days after the start of symptoms.

### Doel van het onderzoek

We hypothesis that a immediate invasive strategy is superior to an delayed invasive strategy in patients with a transient ST segment elevation myocardial infarction.

### Onderzoeksopzet

cardiac MRI at 4 days
cardiac MRI at 4 months

**Onderzoeksproduct en/of interventie**

The patients will be randomized to either the immediate or delayed coronary angiography and subsequent revascularisation group

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Age > 18

- clinical presentation of an acute STEMI including chest pain and ST-segment elevations on the ECG of at least 2 mm in 2 standard limb leads or in 2 contiguous chest leads on the

LifeNet ECG.

- complete normalization of ST-segment elevations and resolution of symptoms on the coronary care unit, with or without initial treatment of sublingual nitrate, heparin, P2Y12 inhibitor and/or aspirin.

- analysis in the study requires additionally that the patient can be followed for at least 12 months after the index admission.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- previous myocardial infarction
- refractory ischemia, major arrhythmias, hemodynamic instability or heart failure requiring immediate catheterization

- alternative causes of transient ST-segment elevation other than myocardial infarction.
- refusal or inability to give informed consent.

- GFR<30 ml/min.

- other contraindications for MRI

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

### Deelname

Nederland
Status: Werving nog niet gestart

| | |
|---|---|
| (Verwachte) startdatum: | 01-11-2013 |
| Aantal proefpersonen: | 140 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40420
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3984 |
| NTR-old | NTR4156 |
| CCMO | NL44982.029.13 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON40420 |

# Resultaten

**Samenvatting resultaten**
N/A