# Rapid detection of minimal, acute myocardial necrosis with a sensitive assay for the quantification of cardiac troponin I

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To establish the value of a new, sensitive tropnion I assay in the rapid diagnosis of minimal myocardial damage. To establish whether BNP concentration in the blood of patients with acute, minor myocardial damage has prognostic significance.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational non invasive

# Summary

### ID

NL-OMON30859

**Source** ToetsingOnline

#### **Brief title**

Detection of myocardial damage with a sensitive troponin assay

### Condition

• Myocardial disorders

**Synonym** acute coronary syndrome, myocardial infarction

#### **Research involving**

Human

### **Sponsors and support**

#### Primary sponsor: Catharina-ziekenhuis

1 - Rapid detection of minimal, acute myocardial necrosis with a sensitive assay for ... 30-05-2025

**Source(s) of monetary or material Support:** Materiaalkosten door fabrikant van de diagnostische testen; overige kosten door Catharina Ziekenhuis, Siemens

### Intervention

Keyword: BNP, instable angina pectoris, NSTEMI, troponin

### **Outcome measures**

#### **Primary outcome**

Troponin concentrations in patients with acute myocardial damage in comparison

to patients without damage.

#### Secondary outcome

Troponinconcentrations in relation to other biochemical markers of myocardial

damage (CKMBmass, myoglobin).

Correlation between BNP and myocardial morbidity and mortality within one year

after BNP measurement.

# **Study description**

### **Background summary**

Different biochemical markers are used for detection of ischemic damage to the heart. A new, sensitive assay for troponin I is available that reliably detects minimal elevation of troponin. This assay may be able to confirm or rule out ischemic damage to the heart early after onset of symptoms. BNP concentration is elevated in plasma from patients with a decreased myocardial function.

### **Study objective**

To establish the value of a new, sensitive tropnion I assay in the rapid diagnosis of minimal myocardial damage. To establish whether BNP concentration in the blood of patients with acute, minor myocardial damage has prognostic significance.

### Study design

2 - Rapid detection of minimal, acute myocardial necrosis with a sensitive assay for ... 30-05-2025

Restrospective, observational study.

Serial troponin measurements are done in time after a patient is admitted to the hospital with chest pain symptoms. The diagnostic utility of troponin (sensitivity, specificity, predicitive values) for diagnosis of myocardial damage is assessed.

BNP concentration is measuired upon admission and patient charactersitics one year after the initial event are correlated with BNP concentrations.

#### Study burden and risks

neglectable, one to two extra venipunctures per patient

# 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**

chest pain

# **Exclusion criteria**

ST elevation myocardial infarction

# Study design

# Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2007
Enrollment:	350
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	04-09-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

# **Study registrations**

4 - Rapid detection of minimal, acute myocardial necrosis with a sensitive assay for ... 30-05-2025

# 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 CCMO **ID** NL16413.060.07