# Influence of renal function on the circadian variation of cardiac troponin

Published: 26-05-2014
Last updated: 21-04-2024

To study the effect of renal clearance on the biological variation and the circadian rhythm of cardiac troponin.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON41818

**Source**
ToetsingOnline

**Brief title**
Circadian variation of cardiac troponin in CKD

### Condition

- Coronary artery disorders
- Renal disorders (excl nephropathies)

**Synonym**
Chronic Kidney Disease, impaired renal function

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht
**Source(s) of monetary or material Support:** Stichting de Weijerhorst

## Intervention

**Keyword:** Cardiac Troponin, Chronic Kidney Disease, Circadian variation

## Outcome measures

### Primary outcome

Concentrations of cardiac troponin T and I over 24 hours, after one week, after one month and after three months

### Secondary outcome

Measures of:

* Basic clinical chemistry parameters to verify a non-disturbed day-night rhythm; such as cortisol, creatine kinase and electrolyte concentrations

* Basic clinical chemistry, haematological and endocrinological parameters to assess the variation of these parameters in subjects with diminished kidney function

* 24 hour automatic blood pressure measurements

* Albumin concentration and hematocrit values, to correct for hydration status.

* Concentration of creatinine, to estimate the glomerular filtration rate.

* Urine concentrations of creatinine, electrolytes and cardiac markers.

# Study description

### Background summary

Cardiac troponin is the preferred biomarker for the diagnosis of acute myocardial infarction. Whereas the diagnosis is based on an increase and/or decrease in the concentrations of cardiac troponins with at least one value above the 99th percentile value of the reference population together with the evidence of ischemia, serial sampling is needed. A recent study by our group showed a circadian rhythm in cardiac troponin levels. This circadian rhythm is

important regarding the interpretation of the serial cardiac troponin levels. It is not clear whether this rhythm is present in subjects with renal impairment. This study will assess the effect of renal clearance on the circadian rhythm of cardiac troponins.

### Study objective

To study the effect of renal clearance on the biological variation and the circadian rhythm of cardiac troponin.

### Study design

Observational study (with invasive measures) consisting of one wake- and sleep cycle with a total duration of 26 hours. Participants will come back to the laboratory for short visits after one week, one month and three months.

### Study burden and risks

The risks associated with the proposed study are low. At the insertion site of the intravenous catheter and venepuncture, a hematoma could occur. Disadvantages of participating in this study for participants are the time investment and the burden. Participants do also need to travel to the university.

## Contacts

**Public**
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
**Scientific**
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Individuals (age >18 years) with chronic kidney disease (CKD) stage 3 (eGFR 30*59 mL/min/1.73m2) and stage 4 (eGFR 15*29 mL/min/1.73m2) without dialysis and with no evidence of active cardiac disease (abscence of: angina pectoris, cardiomyopathy and myocarditis) (age >18 years) will be recruited to participate in our study.

### Exclusion criteria

- acute myocardial infarction (AMI) in the last year.
- anaemia (Hb < 6.5 mmol/L)
- pulmonary embolism in the last six months

## Study design

### Design

**Study type:** Observational invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-09-2014 |
| Enrollment: | 25 |

| | |
|---|---|
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 26-05-2014 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 22-12-2014 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

## 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 |
|---|---|
| CCMO | NL48734.068.14 |

## Study results

| | |
|---|---|
| Date completed: | 13-01-2016 |
| Actual enrolment: | 20 |