Circadian variation of cardiac troponin

Published: 05-12-2012
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To assess the circadian variation of cardiac troponins in individuals without any evidence of active cardiovascular disease.

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

Summary

ID

NL-OMON39553

Source
ToetsingOnline

Brief title
Circadian variation of cardiac troponin

Condition

- Myocardial disorders

Synonym
acute myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac troponin, circadian variation, random biological variation

Outcome measures

Primary outcome

24 hour concentrations of cardiac troponin T and I.

Secondary outcome

- Basic clinical chemistry parameters to verify a non-disturbed day-night

rhythm; such as cortisol, creatine kinase, electrolyte concentrations

- Daytime blood pressure profile.

- Albumin concentration and hematocrit values

- Concentration of creatinine

Study description

Background summary

Acute myocardial infarction (AMI) is defined by an increase and/or decrease in the concentration of cardiac troponin, with at least one value above the 99th percentile value of the reference population together with evidence of ischemia. An objective tool to determine the magnitude of the cardiac troponin change is the use of reference change values (RCV). The basis for this tool is that, for a change to be significant, the difference in serial results must be greater than the inherent variation in two test results. The inherent variation of a laboratory test result is composed of analytical and within-subject biological variation. The assessment of these variance components in the case of cardiac troponin testing is usually conducted with individuals without any evidence of active cardiovascular disease. These calculations cannot be done with AMI patients because AMI is a dynamic disease with changing cardiac troponin concentrations. However, an important requirement to use RCVs is that the concentrations of cardiac troponins fluctuate randomly around a homeostatic set point in cardio-healthy individuals. Verification of this important condition has never been performed, and violation of this condition would preclude the use of RCV*s in clinical practice.

Study objective

To assess the circadian variation of cardiac troponins in individuals without

any evidence of active cardiovascular disease.

Study design

Interventional study consisting of one wake- and sleep cycle with a total duration of 26 hours.

Study burden and risks

There are no direct benefits for the participating subjects. The risks associated with the proposed study are low. At the insertion site of the intravenous catheter, a hematoma could occur.

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

Individuals with no evidence of active cardiovascular disease; age between 18 and 85 years

Exclusion criteria

History of acute myocardial infarction in the last year

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):	29-01-2013
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	05-12-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	23-05-2014
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	NL42592.068.12

Study results

Date completed:	23-05-2014
Actual enrolment:	24