The value of high-sensitive troponin T in the detection of an acute myocardial damage after elective electric cardioversion.

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1. Measurement of the hsTnT value in patients undergoing elective ECV in order to determine AMI.2. Identification of characteristics related to an minimal increase of hsTnT value (

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON38474

Source
ToetsingOnline

Brief title
ISOTEC

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electrocardioversion, High-sensitive troponine T, Myocardial damage

Outcome measures

Primary outcome

Acuut myocardialinfarction is proved by a high-sensitive Troponin T value of

above 50 ng/L or above 14 ng/L combined with an increase of hsTnT for at least

with 7 ng/L within 2 hours in patients undergoing an elective cardioversion for

atrial tachyarrhythmias.

Secondary outcome

Identification of characteristics related to a minimal increase of hsTnT value

(<14 ng/L).

Study description

Background summary

The measurement of cardiac troponins, biomarker, in patients suspected of an acute myocardial infarction (AMI) is a standard technique. High-sensitive troponins (hsTnT) are the most recent biomarker of AMI, which is included in the guidelines. Electric cardioversion (ECV) might cause myocardial damage. It is unknown whether the damage creates an AMI. Prior troponins studies couldn*t determine AMI. HsTnT might be able to detect AMI after ECV.

Study objective

1. Measurement of the hsTnT value in patients undergoing elective ECV in order to determine AMI.
2. Identification of characteristics related to an minimal increase of hsTnT value (<14 ng/L).

Study design

Inclusion of patients with an atrial tachyarrhythmia requiring elective electric cardioversion at the cardiology department. Prior ECV blood samples

are collected, extra study blood samples (hsTnT and CK) will be collected. Two and four hours after ECV study blood samples will be collected. During hospitalization heart rhythm will be monitored continuously. In case of significant elevated hsTnT levels the study protocol will be switched to the standard AMI protocol. In all other cases the patient will be discharged after four hours. An appointment for the next day at the outpatients clinic will be made in order to asses an electrocardiogram and the last study blood samples. Clinical data will be obtained from electronic patients files.
Three months after the ECV the electronic patients files will be consulted in order to define any incidence of AMI in past three months.

Study burden and risks

Patient*s hospitalization will be prolonged by one hour with continuous rhythm monitoring. During vena punction extra blood will be taken and 3 times an extra vena punction will take place. The vena punction can be complicated with a local hematoma.

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

1. Atrial arrhythmias requiring electric cardioversion in an elective setting
2. Competent adults
3. Patients 18 year old or >18 years

Exclusion criteria

1. Electric cardioversion in an emergency setting
2. Incompetent adults
3 Patients <18 year old

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	20-11-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL43530.078.13