Inflammation, excacerbation of heart failure, and ventricular tachyarrhythmias in stable heart failure patients with implantable cardioverter-defibrillator.

Published: 16-01-2007
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The aim of the present study is to evaluate whether there is an association between biomarkers (hs-CRP and BNP)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON30360

Source
ToetsingOnline

Brief title
Biomarkers and ventricular tachyarrhythmias

Condition

- Cardiac arrhythmias

Synonym
Sudden cardiac death, ventricular arrhythmias

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: C-reactive protein, Heart failure, Implantable cardioverter-defibrillator, Ventricular arrhythmias

Outcome measures

Primary outcome

The association between ventricular arrhythmias and biomarkers (hs-CRP and

BNP).

Secondary outcome

NA

Study description

Background summary

High-sensitivity C-reactive protein (hs-CRP) levels have been shown to predict cardiovascular risk. Sudden unexplained death (SUD) has been preceded by intraindividual increases in hs-CRP. It is generally assumed that SUD is triggered either by an acute coronary syndrome or by ventricular arrhythmias. On the other hand, B-type natriuretic peptide (BNP) is a powerful biomarker for the diagnosis in heart failure patients. Ventricular arrhythmias are common in heart failure patients. Some data suggested a relationship between BNP and arrhythmogenesis.

Study objective

The aim of the present study is to evaluate whether there is an association between biomarkers (hs-CRP and BNP)

Study design

A single center prospective observational study.

Study burden and risks

There is no additional risk for the patients. Patients will visit the outpatient clinic at regular standard intervals. During this visit, blood

samples will be drawn.

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

Patients with a ClassI/Class II indication for ICD therapy
Patient with NYHA Class II and higher

Exclusion criteria

Replacement of a pulsegenerator
Permanent atrial fibrillation

Life expectancy < 1 year

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-04-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2007
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	NL14901.078.06