

Detection of myocardial damage after device implantation

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21848

Source

NTR

Brief title

ISOTONE

Health condition

Pacemaker and ICD implantation

High-sensitive troponin T

Myocardial damage

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam

Source(s) of monetary or material Support: dr. N.M.S. de Groot (zie contact persoon)

Intervention

Outcome measures

Primary outcome

The value of high-sensitive troponin T after pacemaker or ICD implantation.

The study endpoint is reached after a follow-up period of 6 months unless an acute

myocardial infarction occurs before that moment

Secondary outcome

Patient and procedural characteristics that might influence the outcome of the main study parameter

Study description

Background summary

To examine the range of values of hsTnT between patients after implantation of a device ((bi-ventricular) ICD or pacemaker (PM)) in order to define new hsTnT reference values.

Study objective

Within 24 hours after implantation, high-sensitive troponin T is elevated as a result of myocardial damage

Study design

Between 12 and 24 hours prior to device implantation, one blood sample will be taken.

In addition, 3, 6 and 24 hours after device implantation new blood samples will be obtained

Intervention

In each patient, 4 blood samples will be taken

Contacts

Public

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Eligibility criteria

Inclusion criteria

Adults scheduled for pacemaker or ICD implantation

Exclusion criteria

Mental disability

Acute myocardial infarction <30 days before implantation

Congenital heart defects

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	262

Type:

Anticipated

Ethics review

Not applicable

Application type:

Not applicable

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
NTR-new	NL4500
NTR-old	NTR4676
Other	Erasmus MC : METC

Study results