Prospective Assessment of Risk Factors for Appropriate ICD Intervention in Patients with Ischemic Cardiomyopathy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20942

Source
NTR

Brief title
PARCADIA

Health condition

ischemische cardiomyopathie, hartfalen
ischemic cardiomypathy, heart failure

Sponsors and support

Primary sponsor: BIOTRONIK SE & Co. KG
Woermannkehre 1
D - 12359 Berlin
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Source(s) of monetary or material Support: BIOTRONIK SE & Co. KG
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Intervention

Outcome measures

Primary outcome

The primary objective of the clinical investigation is to determine whether there is a relationship between appropriate ICD intervention (shock or ATP) and the Relative Infarct Transmurality (RIT) obtained from Late Gadolinium Enhanced Cardiac Magnetic Resonance (LGE-CMR) imaging in patients with ischemic cardiomyopathy, receiving an ICD for primary prevention (MADIT II population).

Secondary outcome

The secondary objectives of the clinical investigation are to identify baseline risk factors for appropriate ICD intervention determined before ICD implantation and to provide sufficient clinical data for a future confirmatory clinical investigation:

1. Identify a RIT cut-off value as a baseline risk factor that can predict appropriate ICD intervention;

2. Identify other baseline risk factors that can predict appropriate ICD intervention;

3. Design a risk score system, based on risk factors in Coumel categories including trigger (PVC/hr), modulation (HRV) and substrate (RIT).

Study description

Background summary

In the present clinical investigation, we will perform an analysis of baseline risk factors to identify predictors for appropriate ICD intervention in patients with ischemic cardiomyopathy receiving an ICD for primary prevention. The study will be performed in centres in The Netherlands.

Study objective

The primary alternative hypothesis states that the mean relative infarct transmurality (RIT) is different in patients with (RITshock or ATP) and without appropriate ICD intervention, i.e. shock or ATP.

Study design

Patients will be seen by the investigator at the enrolment visit, pre implant screening, ICD implantation, pre-hospital discharge
visit, and follow-up (FUP) visits at 2, 6, 12, 18, 24 months including home monitoring. Additional routine FUP every 6 months until study termination after last enrolled patient has completed 2 years FUP.

Intervention

ICD implantation. Patients are alreay planned for ICD. So they will also receive an ICD when they are not participating in the study.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient with ischemic cardiomyopathy indicated for a de novo ICD implantation for primary prevention, according to ESC guidelines or local standards (MADIT II population);

2. Written informed consent / willingness and ability to comply with the protocol.

Exclusion criteria

1. Contraindication for MRI;

2. Severe renal dysfunction (stage 4 or 5) resulting in contra-indication for the admission of gadolinium during MRI;

3. Indication for secondary prevention ICD implantation;

4. Class I indication for cardiac resynchronization therapy;

5. Heart failure with New York Heart Association functional class IV;

6. LV ejection fraction >40%;

7. Age <18 years and >85 years;

8. Women that are pregnant, lactating or planning to become pregnant;

9. Participating in any other clinical trial with active intervention(s) during the course of this study;

10. Life expectancy less than 1 year.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2012
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-03-2012
Application type:	First submission

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	NL3131
NTR-old	NTR3331
Other	METC : 11.10115
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A