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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20942

Bron
NTR

Verkorte titel
PARCADIA

Aandoening

ischemische cardiomyopathie, hartfalen
ischemic cardiomypathy, heart failure

Ondersteuning

Primaire sponsor: BIOTRONIK SE & Co. KG
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-04-2012
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-03-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3131
NTR-old	NTR3331
Ander register	METC : 11.10115
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A