Non-Invasive epiCardial and Endocardial mapping of Idiopathic Ventricular Arrhythmias

Gepubliceerd: 15-02-2019 Laatst bijgewerkt: 13-12-2022

We hypothesize our body surface mapping system will be able to detect origin of idiopathic ventricular arrhythmia with high accuracy.

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

Samenvatting

ID

NL-OMON21606

Bron
NTR

Verkorte titel
NICE-IVA

Aandoening

Idiopathic ventricular arrhythmia

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: Medisch Spectrum Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Measure of agreement between the calculated origin of ventricular arrhythmia via our

mathematical model versus observed origin of ventricular arrhythmia as Rhythmia© mapping system.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale
Idiopathic ventricular arrhythmias mostly originate in the outflow area of the heart. This is a complex anatomic area consisting of the right ventricular outflow tract, pulmonic artery, left ventricular outflow tract, aortic cusps, coronary sinus as well as the cardiac veins, mitral annulus and epicardial anterior crux.
Detailed data on the site of origin obtained by a non-invasive mapping tool such as integrated electrocardiographic mapping prior to the procedure may facilitate future mapping procedure by narrowing down the number of potential anatomical structures from which the ventricular ectopy may originate.
Thus, procedure time can be shortened in addition to achieving a reduction in the number of anatomical structures that needs to be mapped invasively.

Objective
Non-invasive localization of the origin of idiopathic ventricular arrhythmias

Study design
Observational study

Study population
Patients eligible for radiofrequency catheter ablation of idiopathic ventricular extrasystole and/or (non-)sustained monomorphic ventricular tachycardia, who are able to comprehend the study purposes as well as procedure and provide us with informed consent.

Intervention
Patients who are scheduled to undergo radiofrequency ablation of symptomatic, idiopathic ventricular ectopy are eligible for this study. All patients will undergo cardiac (diffusion-) magnetic resonance imaging (MRI) as part of standard workup before ablation.
Prior to electrophysiology study, an extended, 64-channel, body surface electrocardiogram of the spontaneous ventricular ectopy will be obtained. This ECG-data combined with findings of MRI will be fed into a mathematical model capable of reconstructing epicardial and endocardial activation maps to estimate the site of origin of the ventricular ectopy.

Main study parameters/endpoints
Two primary endpoints have been established.
First, measure of agreement between the calculated origin of ventricular arrhythmia via our mathematical model versus observed origin of ventricular arrhythmia as Rhythmia© mapping system.
Second, accuracy of the NI-ECG in predicting the origin of ventricular arrhythmia by

calculating the mean difference in millimetres between observed site of origin and calculated site of origin.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Patients will have to undergo one additional extended body surface electrocardiographic (ECG) registration by means of a 64-electrode set. A MRI will be performed as part of standard clinical care and it will be used to reconstruct cardiac and thoracic anatomy as well as geometry. There is no additional risk to our patient population, since no additional invasive procedures are required. All patients will receive standard care prior to, during and after procedure.
There is no direct potential benefit of participating in this study. Future mapping procedures may become more efficient, since endocardial and epicardial activation have been visualized prior to start of the ablation procedure.

Doel van het onderzoek

We hypothesize our body surface mapping system will be able to detect origin of idiopathic ventricular arrhythmia with high accuracy.

Onderzoeksopzet

Submitted to METC Twente

Onderzoeksproduct en/of interventie

Prior to electrophysiology study, an extended, 64-channel, body surface electrocardiogram of the spontaneous ventricular ectopy will be obtained. This ECG-data combined with findings of MRI will be fed into a mathematical model capable of reconstructing epicardial and endocardial activation maps to estimate the site of origin of the ventricular ectopy.

Contactpersonen

Publiek

Medisch Spectrum Twente
Nejra Kabašaj

+31631751066

Wetenschappelijk

Medisch Spectrum Twente
Nejra Kabašaj

+31631751066

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Patients, without demonstrable cardiac disease, scheduled for elective radiofrequency catheter ablation of symptomatic, ventricular monomorphic tachycardia or extrasystole
2) Age 18 years and older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Unwillingness to participate in study or sign informed consent
2) Linguistic barrier in communication
3) Unable to undergo cardiac MRI (cardiac device, claustrophobia, implants)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2019
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	15-02-2019
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	NL7529
Ander register	METC Twente : METC/18333.kab

Resultaten