Non-Invasive Epicardial and Endocardial Mapping of Idiopathic Ventricular Arrhythmias

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Non-invasive localization of the origin of idiopathic ventricular arrhythmias

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON48050

Source
ToetsingOnline

Brief title
NICE-IVA

Condition

- Cardiac arrhythmias

Synonym
chamber dysrhythmia, ventricular ectopy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: ziekenhuis zelf;Medisch Spectrum Twente

Intervention

Keyword: Body surface potentials, Electro-anatomical model, Idiopathic ventricular arrhythmia

Outcome measures

Primary outcome

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 difference in millimetres between observed site

of origin and calculated site of origin.

Secondary outcome

N.a.

Study description

Background summary

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 coronary 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.

Study objective

Non-invasive localization of the origin of idiopathic ventricular arrhythmias

Study design

Observational study

Intervention
Patients who are scheduled to undergo radiofrequency ablation of symptomatic, idiopathic ventricular ectopy are eligible for this study. All patients will undergo cardiac 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 cardiac 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.

Study burden and risks

Patients will have to undergo one additional, extended body surface electrocardiographic (ECG) registration by means of a 64-electrode set. The cardiac images obtained with the clinically indicated MRI 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.
No direct personal benefit can be gained from participating in this study. Our participants do contribute to knowledge regarding the use of our specific body surface mapping system.

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

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

Exclusion criteria

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)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	16-10-2019
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Body Surface Mapping systeem
Registration:	No

Ethics review

Approved WMO Date:	12-03-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL68262.044.18
Other	nog niet toegewezen