Prospective use of Philips *iSuite* electroanatomical mapping system in addition to standard CMR-guided electrophysiological procedures.

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The primary objective of this study is to investigate the feasibility of iSuite to create an electroanatomical map of the heart based on which the real-time location of the catheters can be correctly and reliably visualized during CMR-EP

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

Summary

ID

NL-OMON54396

Source
ToetsingOnline

Brief title
Use of "iSuite" during CMR-guided electrophysiological procedures.

Condition

- Cardiac arrhythmias

Synonym
Cardiac arrhythmia; cardiac heart rhythm disturbance.

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - CMR-guided electrophysiological procedure., - Electroanatomical mapping system

Outcome measures

Primary outcome

Successful creation of an electroanatomical map of the heart based on which the real-time location of the catheters can be correctly and reliably visualized during CMR-EP.

Secondary outcome

- Procedural success as measured by electrical and anatomical confirmation of a complete ablation lesion at the end of the procedure.

- Procedure-by-procedure change in procedural times and total amount of CMR images made prior to the first ablation lesion.

- Periprocedural complication rate.

- Anatomical confirmation of chronic ablation lesion on the CMR at 3- and 12-month follow-up.

Study description

Background summary

Electrophysiological (EP) study and radiofrequency catheter ablation is an important treatment strategy for patients with symptomatic cardiac arrhythmias. Historically, the catheter navigation during EP study is guided by fluoroscopy and an electroanatomical mapping system (EAM). Currently, *zero fluoroscopy* EP procedures are gaining popularity, with intracardiac echocardiography, use of EAM-only and cardiac magnetic resonance imaging (CMR) as important imaging tools to replace fluoroscopy. In a CMR-guided electrophysiological procedure

(CMR-EP), magnetic resonance imaging (MRI) offers real-time visualization of the heart, the catheters and concurrent visualization of the neighbouring (extra)cardiac structures. In addition, MRI is able to differentiate specific tissue types and structures, both healthy and diseased, which can aid in the diagnostic and therapeutic process. In the standard CMR-EP set-up the treating electrophysiologist uses the anatomical and structural information from the MRI-scanner and the electrical activity directly measured with the MRI-compatible catheters to perform the procedure. However, an EAM that gathers the electrical information to create an electroanatomical map and integrates this map with the real-time MRI images is not yet commercially available. A limited number of EAM systems have been developed for CMR-EP, amongst them the Philips interventional MRI suite *iSuite* (henceforward called iSuite), which is yet to be CE marked.

Study objective

The primary objective of this study is to investigate the feasibility of iSuite to create an electroanatomical map of the heart based on which the real-time location of the catheters can be correctly and reliably visualized during CMR-EP

Study design

The study is designed as a prospective single-arm observational open*label single center study.

Study burden and risks

This study will not delay any necessary treatment and the study is not expected to adversely affect outcome. The use of iSuite during the standard CMR-EP is expected to yield no additional risk for the patient.
When the patient gives informed consent to the additional MRI scans at 3- and 12-months follow-up, then a time investment of approximately two times 3 hours (twice an MRI scan plus travel time). The exposure to electromagnetic radiation during two additional MRI-scans post-ablation is expected to carry very low risk.

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

- Already scheduled by the treating electrophysiologist for CMR-EP as standard care for the treatment of a cardiac arrhythmia.
- Minimum age of 18 years old.
- Written informed consent.

Exclusion criteria

- Participation in another investigational study that has not reached its primary endpoint.
- Refusal of data storage until 15 years after end of study.

To be noted: All patients that are included in this study are already scheduled and thus considered eligible for CMR-EP by the treating electrophysiologist. A strict prerequisite for CMR-EP is that the patient has no contraindication for MRI (metallic implant, body weight > 130 kg, pregnancy, breast feeding women, known severe allergy to gadolineum contrast agents, renal failure with eGFR <= 30 mL/min/1,73m2) or contraindication for an EP procedure.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-02-2021
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Philips interventional MRI Suite (□iSuite□)
Registration:	No

Ethics review

Approved WMO Date:	12-11-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	17-07-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL74812.068.20