Comparison of a short versus the conventional stimulation protocol for ventricular arrhythmia induction in patients with non-ischemic cardiomyopathy.

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The primary objective of this study is to compare prospectively, in a randomized fashion, the sensitivity and specificity of the conventional versus a short stimulation protocol for induction of sustained monomorphic VT in patients with NICM.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON45986

Source
ToetsingOnline

Brief title
Induction protocol for ventricular arrhythmias in NICM

Condition

- Cardiac arrhythmias

Synonym
induction of ventricular arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Non-ischemic cardiomyopahtie, Programmed electrical stimulation, Ventricular arrhyhtmias

Outcome measures

Primary outcome

The main study endpoints are 1) Reproducible induction (two times) of sustained monomorphic VT (lasting longer than 30 seconds or requiring immediate termination because of hemodynamic instability), 2) Induction of two episodes of polymorphic VT or VF requiring cardioversion or 3) Non inducibility of any sustained VA from two ventricular sites.

Secondary outcome

The secondary endpoints of the study are:

- to compare the efficiency (in terms of time-to-induction or to time-to-complete the induction protocol) of the conventional versus short protocol of induction.

- in patients scheduled for endocardial VT ablation, the additional yield of induction from a left ventricular (LV) site will be tested

- in patients scheduled for endo- and epicardial VT ablation, the additional yield of induction from an epicardial site will be tested

Study description

Background summary

In patients with coronary artery disease, a short 6-step stimulation protocol for the induction of ventricular arrhythmias (VA) consisting on the application of 4 extrastimuli only has been demonstrated to be as sensitive while more specific than the conventional protocol which includes the application of 1 to 3 extrastimuli in a sequential fashion. Whether these results are applicable to patients with non-ischemic cardiomyopathy (NICM) is unknown.

Study objective

The primary objective of this study is to compare prospectively, in a randomized fashion, the sensitivity and specificity of the conventional versus a short stimulation protocol for induction of sustained monomorphic VT in patients with NICM.

Study design

This is a single-center open randomized controlled study.

Intervention

Both the conventional and the short protocol will be performed in each study patient. The order in wich the protocols are performed will be determined in a random fashion. If sustained monomorphic VT or VF is induced, or if the protocol is completed without induction of VAs, the reproducibility of induction will be tested with the second protocol.

Study burden and risks

In all patients, the electrophysiological study will be clinically indicated, therefore, there are not additional burden of risks to participants. Patients included in the study may benefit from a shortened protocol of induction with a lower rate of induction of VF.

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

Patients with left-dominant NICM with previous documentation of sustained VA (sustained monomorphic VT or VF) or clinically considered to be at high risk for VA (presenting with palpitations or syncope with/or without documented non-sustained VT) scheduled for electrophysiological study with/or without ablation.

Exclusion criteria

- Age < 18 years
- Inadequate patient competence
- Pregnancy
- Inability to comply with the protocol due to haemodynamic instability
- Non-NICM (e.g., prior myocardial infarction, infiltrative cardiac disease such as sarcoidosis, amyloidosis or Chagas cardiomyopathy, arrhythmogenic RV cardiomyopathy/dysplasia, hypertrophic cardiomyopathy, non-compaction cardiomyopathy and congenital heart disease)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-10-2019
Enrollment:	134
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL66415.058.18