Encircling Cryoablation of Ventricular Arrhythmia Concomitant with Left Ventricular Reconstruction. A Comparison of the Effectivity of Combined Endo and Epicardial Cryoablation versus Endocardial Cryoablation alone.

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

Summary

ID

NL-OMON32246

Source
ToetsingOnline

Brief title
Cryoablation of Ventricular Arrhythmia concomitant with LV Reconstruction

Condition

- Cardiac arrhythmias

Synonym
Ventricular Arrhythmia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Encircling Cryoablation, Ischemic Cardiomyopathy, Surgical, Ventricular Arrhythmia

Outcome measures

Primary outcome

This study will test the hypothesis that the combined endo- and epicardial ablation therapy but not the endocardial ablation will result in isolation of the VA substrate and that the combined approach will be more effective in preventing reinducibility and spontaneous occurrence of VA. The main study parameters are acute conduction properties across the ablation line intraoperatively. inducibility of VTs before and after surgery and spontaneous VA as registered by the internal cardiac defibrillator.

Secondary outcome

Secundary study parameters include inducibility of VTs before and after surgery and spontaneous VA as registered by the internal cardiac defibrillator.

Study description

Background summary

Encircling endocardial cryoablation of postinfarction left ventricular (LV) aneurysm without mapping, concomitant with LV reconstruction by endoventricular circular patch plasty can be effective to treat sustained ventricular

tachycardia (VT). However, insights into the underlying mechanism of the procedure (endocardial substrate modification or substrate isolation) are lacking and a significant number of patients remain inducible after surgery. Procedural failure becomes important, if the VT origin is excluded from the endocardium by patch material, preventing catheter ablation

Study objective

The main objectives of this study are (1) to evaluate the acute electrophysiological effect of endocardial versus combined endo/epicardial encircling cryoablation, (2) to determine if substrate isolation can be achieved by endocardial or combined endo/epicardial ablations and (3) to assess whether the combined endo- and epicardial approach is more effective than the endocardial approach alone in preventing inducibility of ventricular arrhythmia.

Study design

A monocenter prospective randomized open-label trail.

Intervention

40 patients are randomized to either both endocardial and epicardial cryoablation of borderzone of myocardial scar or endocardial cryoablation alone.

Study burden and risks

Both surgical endocardial and epicardial cryoablation of borderzone of ventricular myocardial scar are feasible and clinically used treatment modalities. The combined approach of endo and epicardial encircling cryoablation is not expected to carry more risk than the endocardial cryoablation alone. Conduction time measurements done during the surgical procedure to establish the effect of cryoablation take limited time and are not expected to negatively influence the result of surgery.
Furthermore study patients will be treated according to the currently valid treatment protocol.

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

Acceptation for surgical left ventricular reconstruction according to Dor
Spontaneous or inducible ventricular arrhythmia

Exclusion criteria

Age<18 year
Unability to comply with the protocol

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2008
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL20420.058.07