Hsf1 Activators Lower cardiomyocyte damage: Towards a novel therapeutic approach to REVERSE atrial fibrillation.

Published: 27-10-2014
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To elucidate the correlation between proteostasis marker levels in serum and atrial tissue, and initiation and progression of AF in patients.

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

Summary

ID

NL-OMON53108

Source
ToetsingOnline

Brief title
HALT & REVERSE

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: atrial fibrillation, epicardial mapping, heat shock protein, proteostasis markers

Outcome measures

Primary outcome

Clinical characteristics and electrophysiological parameters (e.g. pattern of activation, conduction block, epicardial breakthrough, fibrillation interval) will be correlated with proteostasis marker levels and atrial tissue characteristics. Endpoints are postprocedural development or recurrence of AF, or completion of the five year follow up period.

Secondary outcome

nvt

Study description

Background summary

Mechanisms of both electrical and structural underlying atrial fibrillation (AF) is unclear despite years of intensive research. A potential pathway leading to structural cell damage might explain the mechanism underlying AF. This pathway involves activation of proteostasis markers such as heat shock proteins (HSPs) which have cardioprotective characteristics. Hence, patients with a lower proteostasis marker level might be more prone to structural tissue damage and development or recurrence of AF.
Hypothesis: patient with a low baseline proteostasis marker level such as HSPs are more likely to have atrial electropathology and to develop postprocedural AF.

Study objective

To elucidate the correlation between proteostasis marker levels in serum and atrial tissue, and initiation and progression of AF in patients.

Study design

The HALT & REVERSE is a prospective observational study, with a planned duration of 60 months. Correlation between tissue proteostasis marker levels (in blood and/or atrial appendages), degree of electropathology and development of AF will be studied in patients planned for elective open heart surgery, for elective pulmonary vein isolation (PVI) and patients presenting for electric cardioversion. Epicardial mapping is performed in patients undergoing cardiac surgery. Endovascular mapping will be performed in patients scheduled for PVI. In all patients, proteostasis marker levels will be determined in blood samples. In addition, in patients undergoing cardiac surgery, a small tissue sample of the atrial appendages will be analyzed. Post procedural continuous rhythm monitoring is performed for arrhythmia detection.

Intervention

In patients undergoing cardiac surgery, a mapping procedure is performed, which includes induction of atrial fibrillation.

Study burden and risks

For participants of this study there aren*t any direct benefits. Neither the patient, nor the investigators are in any way compensated for their participation with regards to this study. The risks associated with participation are known to be negligible, since mapping in over 926 patients (QUASAR study, n=466; Halt &Reverse study, n=460) did not cause any complications.

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

Adult patients (>18 yr), scheduled for cardiac surgery (N=1080), pulmonary vein isolation (first time and redo procedures N=100), electrical cardioversion (N=100) or electieve electrophysiological study (controls N=100)

Exclusion criteria

Hemodynamic instability
Usage of inotropic agents
Emergency cardiac surgery

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-12-2014
Enrollment:	1380
Type:	Actual

Medical products/devices used

Generic name:	Multi-electrode array (MEA) type 192p-TUD-V1.3
Registration:	No

Ethics review

Approved WMO Date:	27-10-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-06-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2021
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23418
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49785.078.14
OMON	NL-OMON23418