European CURE AF study, Concomitant Uitlization of Radiofrequency Energy for Atrail Fibrillation

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Primary efficacy objective: to test that patients with permanent or persistent AF and concomitant diseases requiring open heart surgery will be free of AF when treated with the Cardioblate Surgical Ablation System using a modified Maze III procedure...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON33162

Source
ToetsingOnline

Brief title
European CURE AF study

Condition

- Cardiac arrhythmias

Synonym
heart rhythm disease, irregular heart rhythm

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic
Source(s) of monetary or material Support: de sponsor van het onderzoek

Intervention

Keyword: Atrial fibrillation, Concomitant procedure, RF Ablation

Outcome measures

Primary outcome

Occurrence of AF after ablation

Secondary outcome

Use of antiarrhythmic medication and antithromboembolic mediaction after

ablation.

Study description

Background summary

The Cardioblate Surgical Ablation System is cleared in Canada and Europe for ablation of cardiac tissue for the treatment of cardiac arrhythmias. In the United States, the Cardioblate bipolar is approved for soft tissue ablation, while the Cardioblate Pen is approved for cardiac tissue ablation. The purpose of the clinical study is to obtain a labeling claim for the US market that the Cardioblate Surgical Ablation System can be used for ablation of cardiac tissue in the treatment of cardiac arrhythmias such as atrial fibrillation among permanent and persistent AF patients.

Study objective

Primary efficacy objective: to test that patients with permanent or persistent AF and concomitant diseases requiring open heart surgery will be free of AF when treated with the Cardioblate Surgical Ablation System using a modified Maze III procedure.
Primary safety objective: to demonstrate that the Cardioblate Surgical Ablation System can safely treat permanent or persistent AF patients requiring concomitant open heart surgery.
Both the efficacy and the safety objective of this study will be analyzed for patients with permanent AF and patients with persistent AF separately.

Study design

A prospective, non-randomized, multi-center clinical trial

Intervention

Radio frequency ablation of the right and left atrium during open heart surgery

Study burden and risks

The additional time required for the Cardioblate procedure and the potential adverse events related to the Cardioblate procedure are minimal in comparison to the risks associated with the concomitant procedure. Risks associated with use of the Cardioblate Surgical Ablation System and concomitant open heart surgery include but are not limited to pericardial effusion / tamponade, thromboembolism, myocardial infarction, irregular cardiac rhythm, cardiac conduction system damage, heart valve damage, damage to adjacent structures or tissue, such as esophageal perforation, injury or damage to great vessels, tissue perforation, unintended burns and pericarditis.

If the patient*s AF is successfully treated, the patient might be able to discontinue anti-arrhythmic medication, many of which have significant side effects. In addition, anticoagulation medication, if no other indications exist, as well as other therapies being used to treat AF might be discontinued. In addition, the long-term risk for thrombo-embolisms and stroke might be reduced.

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 Documented history of AF
2 Concomitant indication (other than AF) for open-heart surgery
3 Able to take the anticoagulant warfarin
4 Greater than or equal to 18 years of age;
5 Able and willing to comply with study requirements by signing a Patient Informed Consent form.

Exclusion criteria

1 NYHA functional class = IV,
2 Left ventricular ejection fraction < 30%,
3 Left atrial diameter > 7.0 cm,
4 Need for emergent cardiac surgery (i.e. cardiogenic shock) or redo open heart surgery,
5 Previous atrial ablation, AV-nodal ablation, or surgical Maze procedure,
6 Pregnancy or desire to be pregnant within 12-months of the study treatment.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-05-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-11-2009
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	NL27687.060.09