Clinical Trial to Evaluate the Treatment of Atrial Fibrillation Using the Ablation Frontiers Cardiac Ablation System

Published: 31-07-2006
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The study objective is to evaluate the safety and efficacy of the Ablation Frontiers Cardiac Ablation System in the treatment of permanent atrial fibrillation.

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

Summary

ID

NL-OMON31777

Source
ToetsingOnline

Brief title
The Atrial Fibrillation Ablation Pilot Study

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Ablation Frontiers, Inc.
Source(s) of monetary or material Support: Door de industrie/bedrijf

Intervention

Keyword: ablation, atrial-fibrillation, multi-arm catheter

Outcome measures

Primary outcome

Acute

- Use of AFI catheters to achieve procedure success.

- Isolation of all accessible Pulmonary Veins

- Elimination of CFAEs and high frequency intracardiac electrograms mapped and ablated with AFI catheters

- Termination of AF upon leaving EP lab

Chronic

- Eighty percent reduction of sustained atrial fibrillation when evaluated for four consecutive days.

- Off all rhythm control AADs at six months unless concomitant use for other cardiac disease.

Secondary outcome

- Improvement of left atrial size compared to baseline.

- Improvement of LV ejection fraction compared to baseline.

- Improved Symptom Severity Score compared to baseline.

- Improvement in the QoL.

Study description

Background summary

Atrial fibrillation (AF) remains the most commonly treated sustained arrhythmia with about five million sufferers worldwide.
The Ablation Frontiers Cardiac Ablation System has been designed to create safe and effective lesions in the heart providing electrical conduction block to stop the drivers associated with the propagation of AF.

Study objective

The study objective is to evaluate the safety and efficacy of the Ablation Frontiers Cardiac Ablation System in the treatment of permanent atrial fibrillation.

Study design

Prospective, single-arm, multi-center, multi-country, non-randomized trial

Intervention

Treatment of atrial fibrillation using the Ablation Frontiers Cardiac Ablation System.

Study burden and risks

Neurologic Exam; 5 times during Study duration.
Quality of Life Questionnaire; 6 times during Study duration.
7 Days continuous Monitoring; pre-procedure and during 2, 6 and 12 month follow-up.

The Ablation Frontiers Cardiac Ablation System is believed to pose little or no additional risks above other commercialized radiofrequency (RF) ablation systems.
During the Study non commercialized catheters are used.

Contacts

Public
Ablation Frontiers, Inc.

5835-118 Avenida Encinas
Carlsbad, CA 92008
USA
Scientific
Ablation Frontiers, Inc.

5835-118 Avenida Encinas
Carlsbad, CA 92008
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

History of symptomatic permanent atrial fibrillation lasting greater than seven days but less than four years with at least one failed DC cardioversion within the previous two years.

Exclusion criteria

Structural heart disease of clinical significance.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2006
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	ablation catheter
Registration:	No

Ethics review

Approved WMO Date:	31-07-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	21-08-2008
Application type:	Amendment
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	NL12745.100.06