Long-term follow-up of the FAST-Trial; catheter ablation and surgical ablation for the treatment of atrial fibrillation

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To evaluate the long-term (up to 5-years after procedure) efficacy and safety of CA against SA in preventing the recurrence of LA arrhythmias in patients with a history of paroxysmal and/or persistent AF

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON42695

Source
ToetsingOnline

Brief title
Long-term follow-up of the FAST-Trial

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, heart rhythm disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ablation, atrial fribrillation, maze surgery

Outcome measures

Primary outcome

• Freedom from any left atrial arrhythmia with or without the use of anti-arrhythmic drugs

• Freedom from additional catheter ablation or rhythm surgery

Secondary outcome

• Freedom from MACE; Cardiovascular death, Myocardial infarction, Recurrent ischemia requiring PCI or surgery

• Freedom from ischemic stroke

• Freedom from transient ischemic attack

• Freedom from cerebral bleeding

• Freedom from major bleeding needing transfusion

• Overall survival

• Freedom from pacemaker implantation

• Freedom from any LA arrhythmia with or without the use of OAC

• QOL

Study description

Background summary

The FAST-trial is a randomized controlled trial comparing catheter ablation (CA) and surgical ablation (SA) for the treatment of atrial fibrillation (AF) in patients with drug-refractory paroxysmal or persistent AF, and/or enlarged atria, and/or failed previous ablation. SA was found to be superior to CA in

achieving freedom from left atrial (LA) arrhythmia after a 12-month follow-up, albeit at the cost of a higher adverse event rate. The aim of this follow-up study is to ascertain whether the difference in effect between treatment with CA and SA further increases and whether the adverse event rate will be stable over time.

Study objective

To evaluate the long-term (up to 5-years after procedure) efficacy and safety of CA against SA in preventing the recurrence of LA arrhythmias in patients with a history of paroxysmal and/or persistent AF

Study design

This is a multi-centre, prospective cohort study

Study burden and risks

This study involves participants having 7-day holter monitoring and one hospital follow-up visit which will be combined. The visit will be performed at the outpatient clinic of the participating centers. This registry is therefore associated with only minimal burden and no risk for the patient. The patient*s own cardiologist will be informed about the observations made by the holter monitoring. Any new observations could obviously result in any change of treatment. Generally, information from this study will benefit patients with symptomatic drug-refractory paroxysmal or persistent AF and/or enlarged atria and/or failed previous ablation, by allowing doctors to learn more about the best way to treat these patients and improve patient quality of life.

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

It includes the original included population of 124 patients that participated in the FAST trial.

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2015
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	NL55162.100.15