A(f)MAZE-CABG study;A PROSPECTIVE RANDOMIZED TRIAL COMPARING FREEDOM FROM ATRIAL FIBRILLATION AT 1 YEAR POST CABG IN PATIENTS UNDERGOING CONCOMITANT LEFT ATRIAL ABLATION USING HIGH INTENSITY FOCUSED ULTRASOUND (HIFU) VERSUS CABG ALONE IN PATIENTS WITH PERSISITENT OR LONG STANDING PERSISTENT ATRIAL FIBRILLATION ;Study Code: AF07004AF

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Concomitant AF ablation with HIFU in patients with persistent or long standing persistent AF undergoing CABG will be superior in restoring SR, compared with patients with persistent or long standing persistent AF undergoing CABG treated with best...

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

Summary

ID

NL-OMON33667

Source
ToetsingOnline

Brief title
A(f) MAZE-CABG study

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
atrium fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: Atrium fibrillation, HIFU ablation, Pulmonary vein isolation

Outcome measures

Primary outcome

• Freedom from Atrial Arrhythmias (AF, Atrial Flutter, Atrial Tachycardia) at

12 months.

One or more episode(s) (on a 72 hours Holter monitor) of AF, Atrial Flutter or

Atrial Tachycardia lasting > 30 seconds will be regarded as recurrence of

Atrial Arrhythmia according to the Guidelines for Reporting Data and Outcomes

for the Surgical Treatment of Atrial Fibrillation .

Secondary outcome

• Freedom from AF and other atrial arrhythmias at 3, 6, 9 and 18 months post

ablation procedure (determined by 24 hour Holter monitor)

• Freedom from AF and other atrial arrhythmias at 24 months post ablation

procedure (determined by 72 hour Holter monitor)

• AF burden at baseline, 3, 6, 9, 12 18 and 24 months (determined by 24 and 72 hour Holter monitor).

• Morbidity performing concurrent ablation in patients undergoing CABG assessed using length of ICU and hospital stay.

• Incidence of stroke, TIA, PV stenosis, bleeding (any episode of major internal or external bleeding that causes death, hospitalization, operation, pericardiocentesis, or permanent injury (e.g. vision loss) or requires transfusion. A bleeding event is reportable whether or not the subject is taking anticoagulation or antiplatelet drugs), thromboembolic complications (not TIA), subsequent pace maker implantation, and death.

• LV function and dimensions and LA size/transport capability at baseline, 6,12 and 24 months post operatively.

• Incidence of conduction block post ablation both intraoperatively across the pulmonary venous and mitral lines.

• Effect of autonomic ganglia stimulation pre and post ablation intra-operatively (measured by slowing of heart rate)

• Quality of life measurements (SF-36) at baseline, 3, 6, 9, 12,18 and 24 months follow up.

• Health Economic evaluation after 24 months including any intervention and its related costs; all AF-related direct medical costs in inpatient, outpatient and ambulatory setting; drug treatment costs; adverse event treatment costs.

Study description

Background summary

There is a clear need to evaluate the benefit of concomitant AF ablation with HIFU in patients with preexisting persistent or longstanding persistent AF undergoing CABG surgery. A prospective randomized trial comparing ablation and no ablation in patients with persistent or longstanding persistent AF undergoing CABG will determine if there is a benefit associated with concomitant ablation.

Study objective

Concomitant AF ablation with HIFU in patients with persistent or long standing persistent AF undergoing CABG will be superior in restoring SR, compared with patients with persistent or long standing persistent AF undergoing CABG treated with best medical treatment according to ACC/AHA/ESC 2006 guidelines and no AF ablation.

Study design

This study will be a single blinded, prospective, randomized, parallel, controlled, multicentric trial. Consented patients who meet the inclusion criteria will be enrolled in the study. They will then be randomized into one of two arms in the study:
• (1) Concomitant HIFU ablation, or
• (2) Best medical treatment
Because of the nature of the ablation procedure, persons performing the cardiac surgery and the EP study intra-operative will not be blinded to the randomization.
The investigators who assess the Holter and echocardiograms and the study nurse will not know which arm the patient is in. The QOL questionnaires will be completed by the patients independently of their families and they will not know which treatment arm they are in.

The sample size is based on the binominal primary endpoint; being free of atrial arhythmias at 12 months postoperative.
A double sided Chi-square test with a significance of 5%, an effective size of 0,30 and a power of 90% will be used to analyse the endpoint.
According to the literature 30% of the patients in the non ablation group and 60% of the patients in the HIFU ablation group will be free of atrial arhythmias 12 months postoperative.

In order to show a significant difference with the two-sided chi-square test with a significance of 5% and a power of 90% a total of 118 patients (59 in

each group) is required. Previous studies have indicated that approximately 20% of the recruited patients will be lost to follow up or will drop out of the study, 10% will die, in 10% a trombus will be detected in the left atrium during TOE before randomization, 10% will undergo a catheter ablation 1 year after the procedure and a safety margin of 10% will be included. Taking the above into account a total of 188 patients (94 patients in each group) will be recruited for the study.

Sample size calculation is based on Cohen, Jacob. 1988. Statistical Power Analysis for Behavioral Sciences, Lawrence Erlbaum Associates, Hillsdale, New Jersey.

Hospital with a large number (>1200) of open heart procedures per year are selected for this study. Approximately 50% of these procedures will be an isolated CABG, and of these 8% (48 patients) will be AF patients. Of these patients 50% (24 patients) will be persistent or long standing persistent AF patients. This is 2% of all CABG patients.

Assuming that 9-11 centers will participate in the study with a mean inclusion rate of 15 patients per year per center, the total recruitement time will be around 18 months. The total follow up time will be 24 months + 30 days. The total duration of the study is estimated to be around 3,5 years.

Per center no more than 30 % of the total amount of patients can be included.

Intervention

Patient will undergo routine CABG. Before the CABG is performed the HIFU ablation procedure is performed on the beating heart. The device used is the Epicor UltraCinch LP Ablation Device. This is a sterile, single-use, tissue ablation device for use in cardiac surgery. It is designed for epicardial application on a beating heart. The UltraCinch LP device consists of an array of cells that deliver acoustic energy to the epicardial surface of the heart. Each cell consists of an ultrasonic transducer, temperature sensor, and saline membrane surrounded by a housing. Saline irrigation membranes provide acoustic coupling for the transducers and cool the epicardial tissue. The ablation array is placed on the target tissue, then secured with tensioning sutures to hold the array in place during the ablation procedure. The device is available in seven sizes, ranging from 7 to 13 ablation cells, which are connected by hinges to allow flexibility when placing the device.

The Epicor LP Positioning and Sizing (LP PAS) System contains sterile, single-use items for use in conjunction with the Epicor UltraCinch* LP Ablation Device during cardiac surgery. The LP PAS System contains an introducer/sizer for determining the appropriate size UltraCinch LP and a set of suture snares and tourniquets for gathering and securing the UltraCinch LP tensioning sutures.

Once the device is secured on the target ablation will start following the treatment algoritm.
After the treatment the CABG is performed.

Study burden and risks

Patients should not experience more pain from the HIFU treatment. The treatment risk's are hardly any higher than the risks of routine open heart surgery.
There is a minor risk on bleeding and cardiac arrhythmias. Both can be treated well.
During the follow-up visits no invasive tests are performed. The FU visits consist of QoL questionnaires, Echocardiograms, 24 and 72 hour Holter monitoring and health economic questionnaires. this will give a time burden but not a physical burden. It will take around nine hours of additional time for the patients to do the follow-up visits.

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

• Legal age in host country
• Scheduled for CABG surgery
• Patient suffering from persistent or long-standing persistent AF
• Patients having the ability to fully comply with the study requirements
• Life expectancy > 2 years
• Patients who have given written informed consent to participate in the study

Exclusion criteria

• Clinically significant local or systemic infection or active endocarditis
• Sutures, pacing/defibrillator leads on the left side of the heart, valve prostheses or rings, or other implanted material in or adjacent to target treatment area.
• Stent in the coronary artery preventing an adequate mitral line
• Any other concomitant operation on the heart
• Previous heart surgery
• Patients who are or may potentially be pregnant
• Previous catheter ablation for atrial arrhythmia
• LA size more than 60 mm in apical view on Trans-Thoracic Echocardiogram (TTE)
• LA thrombus on intra-operative Trans-Oesophageal Echocardiogram (TOE)
• Known contraindication to Amiodarone
• Inability to undergo TOE
• Patients who are unable to give full informed consent for the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2009
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	05-03-2009
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	NL24924.060.08