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A randomised controlled trial to investigate the biochemical and myocardial effects of ablation for atrial fibrillation at concomitant elective cardiac surgery with two different methods, freezing versus heating.

Submission date
16/11/2014

Recruitment status
No longer recruiting

Registration date
05/01/2015

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a heart condition which results in an irregular and often abnormally fast heart rate. Symptoms can include feeling dizzy, being short of breath and palpitations. Having the condition increases the risk of a stroke or, in extreme cases, heart failure. This is because AF can lead to blood clots forming in the heart, which may then be pumped into the general blood circulation and eventually block arteries in the brain. Treatment can include medicines called anti-arrhythmics which help restore a regular heart beat and antithrombotic treatment to stop blood clots from forming. Surgical ablation is a procedure where the diseased area of the heart is destroyed, causing electrically isolating scar lines. The abnormal electrical circuits caused by the diseased area then stops and a normal heartbeat restored. About 5-10% of patients scheduled for cardiac (heart) surgery have AF and surgical ablation is often done at the same time. There are a number of different methods/devices that can be used to destroy the diseased tissue, including freezing (cryo) or heating (using radio frequencies or microwaves) the area. Both these methods have proved to be effective treatments for AF. We want to compare the amount of myocardial (heart muscle) injury, degree of systemic inflammatory response and levels of biochemical markers for cell death in patients when they (a) undergo AF ablation with a cryo-device along with their cardiac surgery (b) undergo AF ablation with a radio frequency (RF) device along with their cardiac surgery and (c) undergo only their cardiac surgery. The atrial function and the heart rhythm will be compared between the groups one year after surgery.

Who can participate?
Adults who are at least 18, about to have elective mitral valve surgery and a history of atrial fibrillation.

What does the study involve?
For each participant, the decision on whether they should have treatment for their AF is made at

a meeting involving cardiologists and cardiac surgeons and it is based on general recommendations. Those participants that are recommended for AF ablation are then randomly assigned to receive either the cryo or RF ablation procedure. The study involves taking blood samples at various points throughout the study, taking myocardial biopsies during the surgery, echocardiography examinations and monitoring the heartbeat.

What are the possible benefits and risks of participating?
There are no benefits for the participants in this study. There might be a slightly increased risk for postoperative bleeding from the myocardial biopsies and the blood samples taken for the study result in some additional blood loss.

Where is the study run from?
Dept. of Cardiothoracic and Vascular Surgery, University Hospital Linköping (Sweden)

When is the study starting and how long is it expected to run for?
September 2013 to December 2018

Who is funding the study?
ALF funding (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Myocardial and systemic response in patient undergoing mitral valve surgery with and without concomitant maze ablation for atrial fibrillation. Patients scheduled for maze treatment are randomized to ablation with cryo or radio frequency (RF) device.

Acronym
RAFT-MSR

Study objectives
1. Atrial fibrillation (AF) treatment with maze procedure concomitant to mitral valve surgery results in higher levels of markers for myocardial injury, higher systemic inflammatory response, and elevated levels of markers for apoptosis.
2. Patients treated with concomitant cryo ablation and RF ablation have different levels of markers for myocardial injury, systemic inflammatory response, and levels of markers for apoptosis.
3. Concomitant AF treatment results in better atrial contractile function at one year follow up.

Added 20/10/2016:
4. Concomitant AF treatment with RF ablation results in better atrial contractile function than concomitant cryo ablation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Linköping, Sweden, 12/12/2012, ref. 2012/371-31

Added 20/10/2018:
refs: 2013/173-32, 2014/451-32, 2015/400-32

Study design
Single-centre, prospective randomized interventional study, also including a non-randomized arm for comparison.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in English. Existing information is written in Swedish.

Health condition(s) or problem(s) studied
Patients with pre-existing atrial fibrillation scheduled for elective mitral valve surgery.

Interventions
1. Non intervention: Mitral valve surgery with or without other cardiac procedures.
2. Intervention 1: Mitral valve surgery with or without other cardiac procedures and concomitant cryo-maze ablation device. Ablation lines according to Cox-Maze IV procedure.
3. Intervention 2: Mitral valve surgery with or without other cardiac procedures and concomitant radio frequency (RF)-maze ablation device. Ablation lines according to Cox-Maze IV procedure.

Intervention Type
Device

Primary outcome measure
1. Markers for myocardial injury: troponin T, creatinine kinase-MB, matrix metalloproteinase-2, tissue inhibitor of matrix metalloproteinase-2, myeloperoxidase (preoperatively, at skin closure, and 3 and 20 hrs postoperatively)
2. Markers for inflammatory response: high sensitive C reactive protein, interleukins, tumour necrosis factors, tumour growth factors (preoperatively, at skin closure, and 3 and 20 hrs postoperatively)

Secondary outcome measures
1. Markers for heart failure and renal function: N-terminal pro brain natriuretic peptide (Nt-proBNP), Creatinine, Cystatin-C (preoperatively, 20 hrs postoperatively, 3 days postoperatively, and Nt-proBNP also at 1 year follow up)
2. Atrial size and contractile function: measured with echocardiography on the preoperative day and at 1 year follow up

Rate of stable sinus rhythm at 1 year follow up: measured with 48 hrs electrocardiogram monitors.

Overall study start date
01/11/2012

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Males and females, age over 18
2. Patients will have been accepted for elective mitral valve surgery (with or without additional cardiac procedures)
3. Patients will have a history of atrial fibrillation (chronic, persistent or paroxysmal),

documented before decision on mitral valve surgery was made
4. All patients will provide written informed consent to participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Total final enrolment
41

Key exclusion criteria
1. Patients having mitral surgery planned through minimal invasive access
2. Patients with active endocarditis
3. Patients having emergency or salvage cardiac operations
4. Patients who are unlikely to be available for follow-up over a two-year period
5. Patients who are deemed not competent to provide consent

Date of first enrolment
01/09/2013

Date of final enrolment
01/01/2018

Locations

Countries of recruitment
Sweden

Study participating centre
University Hospital Linköping
Dept of Cardiothoracic and Vascular Surgery
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Sponsor information

Organisation
University of Linköping, Dept. of Clinical Health and Science

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05ynxx418

Funder(s)

Funder type
Government

Funder Name
County Council of Östergötland - ALF funding (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2020	07/05/2021	Yes	No