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Cryoablation of atrial flutter

Submission date	Recruitment status	[ ] Prospectively registered
23/03/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/04/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/09/2014	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atrial flutter is an abnormality in the beating of the heart, also known as arrhythmias. This arrhythmia can be the cause of stroke, heart failure and eventually death. This heart condition is successfully treatable today with catheter ablation, which destroys a small area of heart tissue that is causing rapid and irregular heartbeats. The aim of this study was to compare two commonly used catheter ablation technologies, namely radiofrequency (burning of the tissue), which is the standard treatment, and cryoablation (freezing of the tissue), which is the alternative treatment.

Who can participate?
All patients regardless of age and gender with clear atrial flutter symptoms can participate in this study.

What does the study involve?
In order to evaluate heart function, patients undergo a clinical examination, ECG recording and echocardiography. Patients will then be randomly allocated to be treated with either radiofrequency or cryoablation. Six months after treatment all patients will be followed up with an out-patient visit and an ECG recording.

What are the possible benefits and risks of participating?
The possible benefits of participating are that cryoablation is practically painless and equally effective to standard treatment (radiofrequency). No risks have been shown in the clinical studies published so far.

Where is the study run from?
The study is run from Karolinska University Hospital, Stockholm, Sweden.

When is the study starting and how long is it expected to run for?
The study ran from January 2007 to November 2010.

Who is funding the study?
Financial support was provided through the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and the Karolinska Institute (Sweden).

Who is the main contact?
Dr Hamid Bastani
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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
Cryothermal versus Radiofrequency Ablation as atrial Flutter Therapy: a randomized comparison

Acronym
CRAFT

Study objectives
Catheter ablation with cryothermal energy is non-inferior to ablation with radiofrequency energy for the treatment of cavotricuspid isthmus (CTI)-dependent atrial flutter (AFL)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board, Stockholm, 2006, ref: 1006-31

Study design
Prospective single-blinded randomized controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Atrial flutter

Interventions
Cryo group:
Cryo was delivered with the use of a steerable 9F, 8-mm-tip catheter (Freezor MAX, CryoCath, Quebec, Canada), which was positioned on the TV annulus. Cryoablation was then performed using a sequential application technique point-by-point from the TV annulus to the inferior vena cava (IVC).

RF group:
RF was performed using a 7F 3.5-mm open-irrigated-tip catheter (Biosense-Webster Inc., Diamond Bar, CA. USA) to create an ablation line between the tricuspid valve and the IVC.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clinical success defined as the freedom from atrial flutter evaluated at the 6-month follow-up.

Secondary outcome measures
1. Acute ablation success defined as bidirectional CTI-block safety assessed by the rate of periprocedural complications, procedure and fluoroscopy times and the level of pain experienced by the patient during the ablation procedure
2. To compare the utility of non-fluoroscopic mapping systems (Ensite NavX) with conventional mapping all patients were also randomized to either fluoroscopy only or Ensite NavX and fluoroscopy

Overall study start date

01/01/2007

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Consecutive patients referred to our institution for ablation therapy of ECG-documented typical CTI-dependent AFL
2. Patients above the age of 18 with symptomatic CTI-dependent AFL documented on a 12-lead ECG with typical ECG appearance of negative saw tooth waves in the inferior limb leads and positive deflections in V1 or positive saw tooth waves in the inferior limb leads and negative deflections in V1
3. Patients with a history of atrial fibrillation included if they had predominant atrial flutter under chronic treatment with class I or III antiarrhythmic agents

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Prior ablation for AFL
2. Atrial flutter related to recently undergone surgery, hyperthyroidism or other severe disease
3. Inability to adhere to the study protocol
4. Pregnancy
5. Predominant atrial fibrillation
6. Contraindication to warfarin

Date of first enrolment
01/01/2007

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Cardiology
Stockholm
Sweden
14186

Sponsor information

Organisation
Karolinska University Hospital (Sweden)

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Sponsor type
University/education

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ROR
https://ror.org/00m8d6786

Funder(s)

Funder type
Government

Funder Name
Stockholm County Council (Sweden)

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Karolinska Institute (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