ISRCTN46898887 https://doi.org/10.1186/ISRCTN46898887

Catheter ablation for the cure of atrial fibrillation study

Submission date
07/10/2015

Recruitment status
No longer recruiting

Registration date
19/10/2015

Overall study status
Completed

Last Edited
20/12/2016

Condition category
Circulatory System

[_] 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 common heart condition, affecting millions of people worldwide. The heart consists of two upper chambers (atria) and two lower chambers (ventricles). Inside the right atrium, a cluster of cells (sinus node) are responsible for firing electrical signals into the heart muscle causing the heart to beat regularly (sinus rhythm). When a person is suffering from AF, the normal signals from the sinus node do not work properly, causing other parts of the atria to fire chaotically. These uncoordinated signals cause the heart to beat irregularly and often very fast (arrhythmia). A common starting point for treating AF is the use of antiarrhythmic drugs. There are several types of antiarrhythmics, however they generally work on the nervous system to prevent abnormal firing of electrical signals. Although these medications are widely used, some people do not respond to treatment. Catheter ablation is a surgical technique which is used to destroy the areas of the heart which are sending out the irregular signals. In the procedure, a thin flexible tube (catheter) is inserted into the groin and guided up to the heart. The tip of the catheter then either burns (radiofrequency ablation) or freezes (cryoablation) the affected areas. This procedure is often very successful, and can completely cure AF in some cases. The aim of this study is to find out whether using catheter ablation at the same time as antiarrhythmic drugs is better at improving sinus rhythm than antiarrhythmic drugs alone.

Who can participate?
Adults with a history of AF who are intolerant to antiarrhythmic drugs or treatment with antiarrhythmic drugs has failed.

What does the study involve?
Participants are randomly allocated to one of two groups. The first group receive a combination of antiarrhythmic drugs and a catheter ablation procedure. The second group receive antiarrhythmic drugs only. All participants are asked to wear an ECG recorder (a device which monitors how well the heart is beating and if there are any irregularities) for three months, which send information to the research team every day. Participants in both groups are also have regular ECG scans over a period of 144 months to find out whether their sinus rhythm has improved and to monitor how many participants in each group survive all together.

What are the possible benefits and risks of participating?
A potential benefit is that patients who receive catheter ablation may show an improvement to their sinus rhythm and may have a better chance of survival. Risks of participating include the general risks associated with antiarrhythmic drugs, as well as a low risk of complications in the catheter ablation group from the procedure.

Where is the study run from?
Casa di Cura San Michele (lead centre) and 3 other hospitals in Italy

When is the study starting and how long is it expected to run for?
February 2002 to May 2015

Who is funding the study?
Casa di Cura San Michele (Italy)

Who is the main contact?
Dr Emanuele Bertaglia

Contact information

Type(s)
Scientific

Contact name
Dr Emanuele Bertaglia

ORCID ID
http://orcid.org/0000-0002-3878-2904

Contact details
via Ca' Rossa, 35
Venice
Italy
30173

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title

Catheter ablation treatment in patients with drug-refractory atrial fibrillation: A prospective, multi-centre, randomized, controlled study

Acronym
CACAF

Study objectives
Concurrent catheter ablation and antiarrhythmic drugs improve maintenance of sinus rhythm in comparison to antiarrhythmic drugs alone in patients with paroxysmal and persistent atrial fibrillation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
San Michele Clinic - Maddaloni (CE) Italy, 07/12/2001, ref: PROT. 22001/CE

Study design
Prospective multi-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Participants are randomly allocated into two treatment groups:

Group 1: Participants in the first group are given antiaarhythmic drugs + catheter ablation (pulmonary vein ablation, right isthmus ablation, left isthmus ablation).

Group 2: Participants in the first group are given antiaarhythmic drugs (preferably amiodarone) only.

In both arms, treatment with antiarrhytmic drugs lasted for the whole follow-up. Patients were followed up by means of a trans-telephonic ECG recorder (Sorin Life Watch, Italy), with data being transmitted daily for 3 months, and by means of standard ECG, Holter monitoring at 1, 4, 7, 10, and 13 months. Thereafter, patients were followed up according to local practice, and

between 1st June 2014 and 31st May 2015 they underwent an in-office examination or a phone interview, and repeated a 12-lead ECG.

Intervention Type
Mixed

Primary outcome measure
Maintenance of sinus rhythm at follow-up, measured with transtelephonic ECG for the first 3 months, with 24 hour Holter monitoring for the first 12 months, and with 12-lead ECG for 144 months.

Secondary outcome measures
Cumulative survival, measured as whether a patient is alive at 144 months follow-up (+/- 3 months).

Overall study start date
01/02/2002

Completion date
31/05/2015

Eligibility

Key inclusion criteria
1. Aged between 18 and 80 years
2. History of paroxysmal (1 or more episodes of AF a month in the last 12 months, each lasting more than 60 min but less than 7 days, with all episodes terminating spontaneously) or persistent (2 or more episodes of AF in the last 12 months , each lasting more than 7 days before being terminated medically) atrial fibrillation first diagnosed at least 6 months before enrollment
3. Intolerant of antiarrhythmic drugs or in whom 2 or more antiarrhythmic drug regimens had failed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
137

Key exclusion criteria

1. Permanent atrial fibrillation (atrial fibrillation was the sole rhythm for the last 12 months)
2. Atrial fibrillation secondary to a transient or correctable abnormality, including electrolyte imbalance, trauma, recent surgery, infection, toxic ingestion, and endocrinopathy
3. Persistence of atrial fibrillation episodes triggered by another uniform arrhythmia (i.e. atrial flutter or atrial tachycardia) despite previous supraventricular tachycardia ablation
4. Intra-atrial thrombus, tumour, or other abnormality precluding catheter insertion
5. Wolff–Parkinson–White syndrome
6. Heart failure with NYHA class III or IV or left ventricular ejection fraction <35%
7. Unstable angina or acute myocardial infarction within 3 months
8. Cardiac revascularization or other cardiac surgery within 6 months or with prior atrial surgery
9. Renal failure requiring dialysis, or hepatic failure
10. An implanted device (pacemaker or cardioverter-defibrillator)
11. Left atrial diameter >60 mm

Date of first enrolment
01/02/2002

Date of final enrolment
30/06/2003

Locations

Countries of recruitment
Italy

Study participating centre
Casa di Cura San Michele
Via Montella, 16
Maddaloni (CE)
Italy
81024

Study participating centre
Ospedale Civile
Via XXIX Aprile, 2
Mirano (VE)
Italy
30035

Study participating centre
Ospedale Civile
Via Battitore, 7/9

Ciriè (TO)
Italy
10073

Sponsor information

Organisation
Casa di Cura San Michele

Sponsor details
via Montella, 16
Maddaloni
Italy
81024

Sponsor type
Hospital/treatment centre

Website
www.clinicasanmichele.com

ROR
https://ror.org/00z3eck08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Casa di Cura San Michele

Results and Publications

Publication and dissemination plan
Planned publication in The Journal of the American Medical Association.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No