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Initial procedure of mini ThoracOthomic ablation of Persistent Atrial Fibrillation versus percutaneous catheter approach

Submission date	**Recruitment status**	[X] Prospectively registered
02/06/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/06/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/06/2014	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Catheter ablation of persistent atrial fibrillation (a surgical procedure that destroys the defective area of the heart) has poor results after performing once. This is due to the occurrence of arrhythmia (irregular heartbeat) in more than one location. Success rate of the this approach becomes appreciable only after repeated procedures. Less invasive approaches, cover large portions of the heart (left atrium) and therefore have a higher success rate and thus reduce the need for repeated procedures. Additionally, recent studies have reported excellent results for step-by-step approach. In this study, we are checking if the step-by-step approach of performing a less invasive surgical treatment first, followed by a second surgical procedure, has a better success rate.

Who can participate?
Adult patients with persistent atrial fibrillation, that lasts for more than 7 days in the last 12 months, can participate in this study.

What does the study involve?
Patients are randomly allocated to one of two groups. One group (treatment group) receives catheter ablation as the first procedure. The other group receives the usual surgical approach as the first procedure. After three months, the patients are evaluated and they are subjected to the second surgical procedure if necessary.

What are the possible benefits and risks of participating?
The expected benefits for the patients in the treatment group is the reduction in the number of procedures required and more stable results. No occurrence of death is reported due to these surgical approaches. The risk of complications is not higher than the common procedures that have a small risk of damage to the gullet (impossible with surgery) and problems in the groin.

Where is the study run from?
The study is run from The Campus Biomedico University, Italy and the Catholic University of the Sacred Heart (the Università Cattolica Sacro Cuore), Italy. Other participants centres are being contacted to enlarge the volume of patients.

When is the study starting and how long is it expected to run for?
The study will start recruiting in September 2013 and is expected to complete by the end of 2015.

Who is funding the study?
It is funded by the participating centres: the Campus Bio-Medico University (Università Campus Bio-Medico), Italy, the Catholic University of the Sacred Heart (Università Cattolica del Sacro Cuore), Italy, and the Magna Graecia University of Catanzaro (Università degli studi Magna Graecia di Catanzaro), Italy.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
AF1/2013

Study information

Scientific Title
A controlled trial to determine whether the minimally invasive surgical ablation of persistent atrial fibrillation performed as the initial procedure is more effective than percutaneous catheter approach in achieving normal sinus rhythm after one year

Acronym
TOP-AF

Study objectives

We are verifying the hypothesis that a staged approach of performing a first minimally invasive surgical ablation of persistent atrial fibrillation followed, in case of recurrence, by a second percutaneous procedure, has a success rate higher than the repeated percutaneous procedures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Campus Bio-Medico University (Università Campus Bio-Medico) Ethics Commission, approval 2013

Added 23/01/2014: The Magna Graecia University of Catanzaro (Università degli studi Magna Graecia di Catanzaro) Ethics Commission, approval 2013

Study design
Prospective controlled unbalanced (2:1) randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Persistent Atrial Fibrillation as defined by the 2012 Focused Updated of the ESC guidelines for the management of AF. Europ Heart J (2012)33:2719

Interventions
Patients will be randomized to the percutaneous catheter (100 patients) or to the Surgical (50 patients) ablation as first procedure. After 3 months they will be re-evaluated according to the same guidelines and will be subjected to a second procedure if necessary. Cross over will be allowed and data analyzed on an 'intention to treat' basis. Primary endpoints are the incidence of sinus rhythm at 6 and 12 months and the proportions of patients requiring a second procedure.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Freedom from AF at 12 months as detected by a 12 leads ECG and a 24 H Holter examination after a 3, 6 and 9 months follow-up
2. A repeated procedure to achieve a 12 months freedom from AF

Key secondary outcome(s))
Any documented atrial arrhythmia like atrial fibrillation (AF) or a trial flutter (AFL) or atrial tachycardia (AT)

Completion date
31/12/2015

Eligibility

Key inclusion criteria
The inclusion and exclusion criteria, definitions and treatment protocols are those reported by the 2012 HRS/EHRA/ECAS expert consensus statement on cathter and surgical ablation of atrial fibrillation. J Interv Card Elecrophysiol (2012);33:171
Inclusion criteria
1. Patients who are 18 years of age or older
2. Patients with persistent AF, which is defined as a sustained episode lasting more than 7 days in the last 12 months
3. Patients with symptomatic AF that is refractory to at least one antiarrhythmic medication. Symptomatic patients are those who have been aware of their AF at anytime within the last 5 years before enrollment. Symptoms may include, but are not restricted to, palpitations, shortness of breath, chest pain, fatigue, left ventricular dysfunction, or other symptoms, or any combination of the above.
4. At least one episode of persistent AF must have been documented by ECG, Holter, loop recorder, telemetry, transtelephonic monitor, or implantable device within last 2 years of enrollment in this investigation.
5. Patients must be able and willing to provide written informed consent to participate in this investigation
6. Patients must be willing and able to comply with all periablation and follow-up requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with paroxysmal AF, whic is defined as a sustained episode lasting >7 days
2. Patients with long-standing persistent AF, which is defined as a sustained episode lasting >1 year
3. Patients for whom cardioversion or sinus rhythm will never be attempted/pursued
4. Patients with AF secondary to a reversible cause
5. Patients with contraindications to systemic anticoagulation
6. Patients with left atrial size ≥55 mm (2-dimensional echocardiography, parasternal long-axis view)
7. Patients with LA thrombi as demonstrated by TEE

Date of first enrolment
01/09/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Italy

Study participating centre
via della balduina 120
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Italy
00136

Sponsor information

Organisation
The Catholic University of the Sacred Heart (Università Cattolica S. Cuore Roma) (Italy)

ROR
https://ror.org/03h7r5v07

Funder(s)

Funder type
University/education

Funder Name
The Campus Bio-Medico University (Università Campus Bio-Medico) (Italy)

Funder Name
The Catholic University of the Sacred Heart (Università Cattolica del Sacro Cuore) (Italy)

Funder Name
Added 23/01/2014:

Funder Name
The Magna Graecia University of Catanzaro (Università degli studi Magna Graecia di Catanzaro) (Italy)

Results and Publications

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?
Protocol article	protocol	26/05/2014		Yes	No