

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

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| Submission date 02/06/2013 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 20/06/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 03/06/2014 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Claudio Pragliola
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Contact information

Type(s)

Scientific

Contact name

Prof Claudio Pragliola

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2013

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 catheter and surgical ablation of atrial fibrillation. J Interv Card Electrophysiol (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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

1. Patients with paroxysmal AF, which 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

ROMA

Italy

00136

Sponsor information**Organisation**

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

Sponsor details

c/o Claudio Pragliola

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Sponsor type
University/education

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

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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 26/05/2014 | | Yes | No |