

Prevention of Post-Operative Atrial Fibrillation

Submission date 12/08/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/09/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/01/2014	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1070948

Study information

Scientific Title
Prevention of post-operative atrial fibrillation: pathophysiological characterisation of a pharmacological intervention based on a novel model of non-hypoxic pre-conditioning

Acronym
POAF

Study objectives

The trial is designed to test the hypothesis that the previous reinforcement of the antioxidant defense system reduces the occurrence of post-operative atrial fibrillation (AF) in patients subjected to cardiac surgery with extracorporeal circulation.

Please note that as of 16/01/2013, the following changes were made to the record:

1. The anticipated start date for this trial was updated from 01/07/2007 to 07/01/2007
2. The anticipated end date for this trial was updated from 01/03/2010 to 31/12/2011

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committees (University of Chile Clinical Hospital, Faculty of Medicine of the University of Chile and Health Ministry of the Chilean Government) approved on the 5th June 2008 (ref: 100)

Primary study design

Interventional

Study design

Double blind placebo-controlled clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-operative atrial fibrillation

Interventions

Oral administration of:

1. Omega-3 polyunsaturated fatty acids: 1 g every 12 hours, beginning 7 days before surgery, until hospital discharge
2. Vitamin C: 500 mg every 12 hours, beginning 2 days before surgery, until hospital discharge
3. Vitamin E: 400 IU daily, beginning 2 days before surgery, until hospital discharge

Total duration of follow-up for all arms: 14 days

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Occurrence of post-operative atrial fibrillation. Basal electrocardiogram for patients in sinus rhythm and electrocardiographic monitoring will be performed throughout the hospitalisation period, in order to detect the occurrence of atrial fibrillation.

Key secondary outcome(s)

1. Biochemical markers of oxidative stress, performed on blood samples withdrawn: 7 and 2 days before surgery, the day of surgery, 8 hours and 4 days after surgery
2. Atrial tissue will be obtained during surgery to be analysed

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Aged between 30 - 80 years, either sex
2. Scheduled for elective coronary artery bypass graft, valve surgery, or mixed
3. In sinus rhythm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Previous heart surgery
2. Pre-operative documented history of chronic or paroxysmal AF
3. Comorbidities such as congenital or cardiac re-operation
4. Advanced hepatic disease (cirrhosis)
5. Chronic renal failure (serum creatinine greater than 2.0 mg/dL)

Date of first enrolment

07/01/2007

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Chile

Study participating centre

Independencia 1027

Santiago

Chile
70058

Sponsor information

Organisation

Fondo de Desarrollo Científico y Tecnológico (Chile)

ROR

<https://ror.org/02ap3w078>

Funder(s)

Funder type

Government

Funder Name

Fondo de Desarrollo Científico y Tecnológico (ref: FONDECYT N° 1070948), Chilean Government (Chile)

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?
Results article	results	15/10/2013		Yes	No