ISRCTN45347268 https://doi.org/10.1186/ISRCTN45347268

Prevention of Post-Operative Atrial Fibrillation

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ramon Rodrigo

Contact details
Independencia 1027
Santiago
Chile
70058

Additional identifiers

Protocol serial number
1070948

Study information

Scientific Title
Prevention of post-operative atrial fibrillation: pathophysyological 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)

Study design
Double blind placebo-controlled clinical trial

Primary study design
Interventional

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)
Ocurrence 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 Nº 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes