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Cardioprotection by Riluzole in Cardiac Bypass Surgery

Submission date 08/06/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/06/2010	**Overall study status** Completed	
Last Edited 28/06/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
26-6-2009V1

Study information

Scientific Title
Cardioprotection by Riluzole in Cardiac Bypass Surgery: A randomised double-blind placebo-controlled trial

Acronym
R-Cardiac

Study objectives
The primary aim of this study is to analyse the effect of Riluzole in preventing myocardial damage post cardiac bypass surgery (CABG).

The primary null hypothesis of this study is that Riluzole treatment will have no effect on myocardial damage post CABG as determined by Troponin rise post surgery.

The secondary aims of this study are to observe the effect of Riluzole on the incidence of atrial and ventricular arrhythmias post CABG and on cardiac function as assessed by transthoracic echocardiography.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Australian Capital Territory Human Research Ethics Committee (ACTHEC) approved on the 12th of March 2010 (ref: ETH7.09.711)

Study design
Single centre randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Cardiac ischaemia treated with coronary artery bypass grafting

Interventions
Clinical trial of Riluzole v placebo, before and following coronary artery bypass surgery.
1. Riluzole oral 100mg / day for 5 pre-operative days, 200mg immediately pre-surgery, and 100mg for 5 days following surgery.

2. Riluzole oral 100mg / day for 5 pre-operative days, 200mg immediately pre-surgery, and placebo (potato starch, identical capsule) for 5 days following surgery.
3. Placebo (potato starch, identical capsule) oral each day for 5 pre-operative days, and for 5 days following surgery.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Troponin levels post CABG. Measured at 2, 3, 6, 8, 12, 24, 48, 72, 96 and 120 hours post surgery in order to calculate the Troponin rise curve. The assay is cTropnin I in plasma (ng/ml).

Secondary outcome measures
1. Incidence of cardiac arrhythmia post CABG. 12 lead ECG will be collected pre op, during surgery and ECG during ICU. Thence patients will wear a holter monitor until discharge home. Repeat 12 lead ECG will be conducted at 6 weeks follow up.
2. Incidence of abnormal findings on echo cardiography. Pre-admission echocardiography will be compared to post operative, Day 4 and 6 weeks echo.
3. Cardiac function will be assessed in all patients using transthoracic echocardiography at baseline and post surgery prior to discharge from hospital. Cardiac parameters will be measured off-line using commercially available software (EchoPac 6.0.1, GE Healthcare). The following parameters will be derived:
3.1. Left ventricular (LV) posterior and septal wall thickness and LV mass
3.2. LV relaxation and filling pressure by Doppler-echo for assessment of diastolic function
3.3. LV ejection fraction
3.4. Left atrial (LA), right ventricular (RV) and LV regional myocardial function by 2D-speckle tracking methods

Overall study start date
01/07/2010

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Participant aged 18 to 75 years of age, either sex
2. Ischaemic heart disease planned for CABG.
3. Participant has anaesthesia risk (ASA) score of 4 or less
4. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Patients who are unable to give informed consent (e.g. poor English language skills)
2. Patients who are to undergo simultaneous valvular surgery in addition to CABG
3. Premenopausal females (Riluzole has not been proven safe in the setting of pregnancy)
4. Patients with an implantable cardiac defibrillator or cardiac pacemaker in situ
5. Patients with existing atrial fibrillation
6. Patients with significant pre-existing hepatic impairment (hepatic enzymes greater than 2x upper normal range)
7. Emergency CABG surgery
8. CABG for other than 2-4 vessels
9. Patients with severe renal failure on dialysis

Date of first enrolment
01/07/2010

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Australia

Study participating centre
Canberra Orthopaedic Group
Deakin
Australia
2600

Sponsor information

Organisation
Canberra Hospital (Australia)

Sponsor details

General Manager
Executive offices
Building 2, Level 3
PO Box 11
Woden
Australia
2606

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04h7nbn38

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Canberra Hospital (Australia) - Trauma and Orthopaedic Research Unit (internal funding)

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