

# Cardioprotection by Riluzole in Cardiac Bypass Surgery

<b>Submission date</b> 08/06/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 28/06/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Paul Smith

**Contact details**  
Canberra Orthopaedic Group  
Clinical Services Building  
173 Strickland Crescent  
Deakin  
Australia  
2600

## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Prevention

### **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(s)**

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).

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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)

**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

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration