

The role of high dose statins in the prevention of postoperative atrial fibrillation in patients undergoing cardiac surgery

Submission date 14/08/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/12/2010	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

Study information

Scientific Title

Study objectives

1. Perioperative treatment with high dose atorvastatin (80 mg once daily) reduces the occurrence of Atrial Fibrillation (AF) following cardiac surgery in the early postoperative period.
2. Perioperative treatment with atorvastatin prevents irreversible perioperative myocardial injury.
3. Metabolic derangements may explain the increased energy demand during AF.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval has been obtained for this study from the Wandsworth Local Research Ethics Committee (reference number: 06/Q0803/37). The study has been registered with the Clinical Trials Unit.

Primary study design

Interventional

Study design

Prospective analysis, randomised, double-blind study.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atrial fibrillation

Interventions

We propose to carry out a randomised, double-blind study of the effect of atorvastatin 80 mg, or placebo on postoperative AF in 450 patients undergoing cardiac surgery. Patients of all ages will be included and those in sinus rhythm will be chosen. Inflammatory markers including C-Reactive Protein (CRP), Matrix MetalloProteinase (MMP) and its inhibitor, will be measured. Both right and, where possible, left atrial tissue will be studied for proteomic analysis. AF will be documented by continuous monitoring in the postoperative period.

The patients will be randomised to the following groups:

1. Patients on statins will be randomised to 10 mg and 80 mg of atorvastatin
2. Patients taking no statins will be randomised to placebo and 80 mg of atorvastatin

The treatments will continue for one week following surgery. Patients will be evaluated in an assessment clinic one week prior to surgery and will be randomised to one of the two groups. If patients have already been on any of the statins, that will be stopped in the clinic. Randomisation will be performed by the Clinical Trials Unit using a minimisation algorithm. All patients will have a trans-thoracic echocardiography performed prior to surgery determining the size of the atria, right and left ventricular function and evidence of thrombo-embolism.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Atorvastatin

Primary outcome(s)

Atrial fibrillation

Key secondary outcome(s)

Thromboembolic episodes (Transient Ischaemic Attacks [TIA]/CerebroVascular Accident [CVA])

Completion date

17/09/2007

Eligibility

Key inclusion criteria

Patients undergoing elective first time Coronary Artery Bypass Graft (CABG) and/or Aortic Valve Replacement (AVR) will be randomised.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. History of atrial arrhythmias
2. Hepatobiliary disease
3. Creatinine more than 180 mmol/l
4. Known intolerance of statins
5. Patients on long-term inhibitors of cytochrome P-450, history of AF, patients on treatment for anti-arrhythmic agents, except those on betablockers

Date of first enrolment

18/09/2006

Date of final enrolment

17/09/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Department of Cardiac Surgery
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
St. George's Hospital Charitable Foundation (UK)

ROR
<https://ror.org/0001ke483>

Funder(s)

Funder type
Charity

Funder Name
St. George's Hospital Charitable Foundation

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	01/01/2011		Yes	No