Amiodarone to reduce post-cardiopulmonary bypass systemic inflammatory response

Submission date 14/11/2005	Recruitment status No longer recruiting	Prospectively registered Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
15/11/2005		[X] Results	
Last Edited 25/09/2009	Condition category Surgery	 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers EK.Nr: 078/2001

Study information

Scientific Title

Acronym APPCIR

Study objectives

The study investigated the anti-inflammatory properties of Amiodarone after coronary-artery bypass surgery using cardiopulmonary bypass (CPB)

Ethics approval required Old ethics approval format

Ethics approval(s) Ethical committee of the Medical University of Vienna

Study design Prospective, double blind, placebo-controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Coronary-artery bypass surgery (CABG) with CPB

Interventions

Placebo or Amiodarone 600 mg/day for seven days orally and 45 mg/hour intravenously (IV) for 48 hours after the start of surgery

Intervention Type Drug

Phase Not Specified

Drug/device/biological/vaccine name(s) Amiodarone

Primary outcome measure C-reactive protein concentration area under the curve (AUC) up to 48 hours after start of surgery

Secondary outcome measures

AUCs of white blood cell count (WBC), fasting blood glucose (FBG), tumour necrosis factor-alpha (TNF-alpha), interleukin 6 and interleukin 10.

Overall study start date

01/04/2002

Completion date

01/03/2004

Eligibility

Key inclusion criteria

Patients older than 40 years and younger than 75 years old undergoing non-emergent coronaryartery bypass surgery (CABG) with CPB were eligible for the study

Participant type(s)

Patient

Age group

Adult

Sex Both

Both

Target number of participants

20-40

Key exclusion criteria

- 1. A history of adverse events to AMIO
- 2. Concurrent treatment with AMIO within four months of enrolment
- 3. The use of antiarrhythmic therapy other than beta-receptor blockers
- 4. Calcium channel blockers or digitalis
- 5. A C-reactive protein (CRP) concentration above normal (>0.5 mg/dl)
- 6. A serum asparate aminotransferase or an alanine aminotransferase concentration four times the upper limit
- 7. Child bearing potential
- 8. An untreated thyroid dysfunction (thyroid-stimulating hormone [TSH] <0.01, >10 miU/ml)
- 9. Chronic renal failure (serum creatinine >114 µmol/l)

10. An ejection fraction <30% (determined either by nuclear, left flourescence ventriculography or echocardiography)

- 11. Diabetes mellitus
- 12. Unstable angina
- 13. A resting heart rate of less than 50 beats per minute
- 14. An active infection
- 15. Malignancy
- 16. Chronic atrial fibrillation

Date of first enrolment

01/04/2002

Date of final enrolment 01/03/2004

Locations

Countries of recruitment Austria

Study participating centre Waehringer Guertel 18-20 Vienna Austria 1090

Sponsor information

Organisation Medical University of Vienna, Department of Cardiology (Austria)

Sponsor details Waehringer Guertel 18-20 Vienna Austria 1090

Sponsor type University/education

ROR https://ror.org/05n3x4p02

Funder(s)

Funder type Not defined

Funder Name

Supported by the Austrian Science Fund (Fonds zur Förderung der Wissenschaftlichen Forschung [FWF]) (Austria) (Grant P 15152)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2007		Yes	No