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Amiodarone to reduce post-cardiopulmonary bypass systemic inflammatory response

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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1090

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 coronary-artery bypass surgery (CABG) with CPB were eligible for the study

Participant type(s)
Patient

Age group
Adult

Sex
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
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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