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Histamine Release and Implications of H1- and H2-Blockade in Adult Cardiac Surgery - A Randomised Controlled Study

Submission date 15/12/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/01/2005	**Overall study status** Completed	
Last Edited 02/05/2014	**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
N/A

Study information

Scientific Title

Study objectives
Systemic inflammatory response is associated with cardiac surgery. Mediators liberated include cytokines and histamine. Histamine is associated with systemic effects like vasodilatation and cardiac dysrhythmias.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Patients will be randomly allocated into two groups.
Group H: this group will receive prophylactic H1- and H2-blockade
Group O: control group with no H1- and H2-blockade (placebo)
The study will be double blinded.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
H1 and H2 blockers

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2005

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Entry criteria: Patients presenting for elective coronary artery bypass grafting (CABG) and valve surgeries using cardiopulmonary bypass.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
1. Patients on heparin or nitrate infusions
2. Patients with known allergies
3. Known asthmatics and patients with severe chronic obstructive pulmonary disease (COPD)
4. Patients on steroids or other immunosuppressive drugs
5. Emergency procedures or re-do operations
6. Patients on regular H1 or H2 blockers

Date of first enrolment
01/02/2005

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
University Hospital of Wales
Cardiff
United Kingdom
CF4 4XW

Sponsor information

Organisation
University of Wales College of Medicine, UK

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/01se4f844

Funder(s)

Funder type
University/education

Funder Name
University of Wales College of Medicine (UWCM) Endowment Fund, UK

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