

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/05/2014	Condition category 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
Dr Cristina Diaz-Navarro

Contact details
University Hospital of Wales
Cardiff
United Kingdom
CF4 4XW
+44 (0)2920743107

Additional identifiers

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration