

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

<b>Submission date</b> 15/12/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/05/2014	<b>Condition category</b> 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

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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**  
Heath Park  
Cardiff  
Wales  
United Kingdom  
CF4 4XW  
HumphreysJM@cf.ac.uk

**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