

Investigation of leukocyte trafficking into skin blisters during cardiopulmonary bypass

| | | |
|--|---|---|
| Submission date 04/07/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 10/07/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/12/2010 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Dorian Haskard

Contact details
British Heart Foundation Cardiovascular Medicine
Imperial College School of Medicine
Hammersmith Hospital Campus
Du Cane Road
London
United Kingdom
W12 0NN

Additional identifiers

Protocol serial number
2003/6589 (NRR No.: N0016131981)

Study information

Scientific Title

Study objectives

We propose that leukocyte extravasation and the release of inflammatory mediators into cantharidin skin blisters will be enhanced during cardiopulmonary bypass and that the effect of aprotinin or off-pump coronary artery surgery will ablate this

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Hammersmith Hospital and Queen Charlotte's Chelsea Hospitals Research Ethics Committee on 15/07/2003, reference number: 2003/6589

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ischaemic heart disease

Interventions

Coronary artery bypass surgery, with or without cardiopulmonary bypass, with or without use of aprotinin infusion

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Aprotinin

Primary outcome(s)

1. Leukocyte trafficking into skin blisters - total and differential count
2. Measurement of inflammatory mediators within blister fluid

Key secondary outcome(s)

Cellular phenotype within blister fluid - activation markers on cell surface

Completion date

14/10/2005

Eligibility

Key inclusion criteria

Primary, elective, coronary artery bypass surgical patients, between ages 45-75 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pregnancy
2. Myocardial infarction in previous six weeks
3. On steroid medication
4. Malignancy
5. Chronic inflammatory disorder

Date of first enrolment

01/01/2004

Date of final enrolment

14/10/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

British Heart Foundation Cardiovascular Medicine

London

United Kingdom

W12 0NN

Sponsor information**Organisation**

Hammesmith Hospital NHS Trust (UK)

ROR

<https://ror.org/056ffv270>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation grant for clinical PhD studentship number: FS/03/065/15951

Results and Publications

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 | 01/05/2008 | | Yes | No |