

Investigation of leukocyte trafficking into skin blisters during cardiopulmonary bypass

Submission date 04/07/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/07/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/12/2010	Condition category Circulatory System	☐ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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