ISRCTN60289857 https://doi.org/10.1186/ISRCTN60289857

Investigation of leukocyte trafficking into skin blisters during cardiopulmonary bypass

Submission date 04/07/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/07/2006	**Overall study status** Completed	
Last Edited 14/12/2010	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Cellular phenotype within blister fluid - activation markers on cell surface

Overall study start date
01/01/2004

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

Age group
Adult

Sex
Both

Target number of participants
48

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
England

United Kingdom

Study participating centre
British Heart Foundation Cardiovascular Medicine
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Hammesmith Hospital NHS Trust (UK)

Sponsor details
Du Cane Road
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England
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Sponsor type
Hospital/treatment centre

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008		Yes	No