# Investigation of leukocyte trafficking into skin blisters during cardiopulmonary bypass

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
04/07/2005		Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/07/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
14/12/2010	Circulatory System			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

Prof Dorian Haskard

### Contact details

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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 London England United Kingdom W12 ONN

# 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