

# Can lung inflammation be reduced by temporarily removing specific white blood cells from the bloodstream?

**Submission date**  
16/04/2009

**Recruitment status**  
No longer recruiting

Prospectively registered

Protocol

**Registration date**  
05/08/2009

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
05/02/2014

**Condition category**  
Injury, Occupational Diseases, Poisoning

Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Trial of monocyte depletion in experimental lung inflammation: a single centre, double-blind, randomised, controlled trial

## Study objectives

In a model of experimental acute lung inflammation in humans, monocyte depletion can ameliorate systemic and pulmonary inflammation.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Lothian research ethics committee (REC) 1 approved on the 11th May 2009 (ref: 09/S1101/27)

## Study design

Single centre double-blind randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Experimental Lung Inflammation

## Interventions

Study A:

To characterise the relationship between blood neutrophil/monocyte accumulation and lung inflammation after inhalation of LPS.

Duration of nebulised LPS intervention: 30 - 60 minutes

Duration of Bronchoscopy and BAL: 30 minutes

Study B:

To characterise the effect of mononuclear cell depletion on lung inflammation.

Duration of Leukapheresis: 3 - 6 hours (3 - 4 blood volume changes)

Duration of Bronchoscopy and BAL: 30 minutes

Study C:

Can lung inflammation be reduced by temporarily removing specific white blood cells from the bloodstream? A randomised, double-blind, placebo-controlled trial.

Duration of nebulised LPS intervention: 30 - 60 minutes

Duration of Leukapheresis: 3 - 6 hours (3 - 4 blood volume changes)

Duration of Bronchoscopy and BAL: 30 minutes

Duration of CT-PET: 1 hour

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Magnitude of LPS-induced neutrophilia after treatment assessed by selective mononuclear leukapheresis, sample taken at 8 hours.

## **Secondary outcome measures**

1. Alveolar pulmonary neutrophil accumulation and injury assessed by bronchoscopy, sample retrieved at 8.5 hours
2. Global pulmonary neutrophil accumulation and injury assessed by positron emission tomography (PET), sample retrieved at 8.5 hours
3. Cytokines in BAL fluid, sample retrieved at 8.5 hours
4. Protein and albumin in BAL fluid, sample retrieved at 8.5 hours
5. Change in oxygen saturation, recordings made every 1 hour (0 - 8 hours, 24 hours and as indicated)
6. Change in serum markers of inflammation, blood drawn 0, 2, 4, 6 and 8 hours (where 0 hours is time just before nebulised LPS)
7. Serial profile of blood neutrophils and monocytes, blood drawn at 0, 2, 4, 6 and 8 hours
8. PET values, scan is at 11 hours
9. Safety and tolerability, measured throughout

## **Overall study start date**

01/08/2009

## **Completion date**

31/07/2011

## **Eligibility**

### **Key inclusion criteria**

Healthy male volunteers aged 18 - 40 years

### **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

42 (Study A: 6; Study B: 6; Study C [RCT]: 30)

**Key exclusion criteria**

1. Aged less than 18 years
2. History of any chronic or ongoing acute illness (with particular reference to asthma, upper respiratory tract infection, lower respiratory tract infection, bronchiectasis, congenital heart disease, ischaemic heart disease, valvular heart disease, diabetes mellitus, chronic renal impairment, urinary tract infection)
3. Current history of smoking
4. Past smoking history amounting to greater than two pack-years
5. Any history of smoking in the last 12 months
6. Reported alcohol intake greater than 21 units per week
7. Any current medication
8. Abnormal physical signs detected at cardiorespiratory examination
9. Temperature greater than 37.3°C
10. Oxygen saturation less than 95% breathing room air
11. Haemoglobin, white cell count or platelet count outside the laboratory reference range
12. Blood sodium, potassium, urea, creatinine, bilirubin, alanine aminotransferase, random glucose or C-reactive protein outside the laboratory reference range
13. Forced expiratory volume in one second (FEV1) or forced vital capacity (FVC) less than 80% predicted
14. FEV1:FVC ratio less than 70%
15. Any cardiorespiratory abnormality detected on chest x-ray
16. Peripheral venous access insufficient to support bilateral 16 gauge cannulae

**Date of first enrolment**

01/08/2009

**Date of final enrolment**

31/07/2011

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Room C2.12, MRC CIR**  
Edinburgh  
United Kingdom  
EH16 4TJ

## **Sponsor information**

### **Organisation**

University of Edinburgh (UK)

### **Sponsor details**

Queen's Medical Research Institute  
47 Little France Crescent  
Edinburgh  
Scotland  
United Kingdom  
EH16 4TJ

### **Sponsor type**

University/education

### **Website**

<http://www.ed.ac.uk/>

### **ROR**

<https://ror.org/01nrxf90>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Sir Jules Thorn Charitable Trust (UK) (ref: DHR/amh)

### **Alternative Name(s)**

The Sir Jules Thorn Charitable Trust

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

## 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?
<a href="#">Results article</a>	results	15/08/2013		Yes	No