ISRCTN42695423 https://doi.org/10.1186/ISRCTN42695423

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

Submission date	Recruitment status
16/04/2009	No longer recruiting
Registration date	**Overall study status**
05/08/2009	Completed
Last Edited	**Condition category**
05/02/2014	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr John Simpson

Contact details
Room C2.12, MRC CIR
Queens Medical Research Centre
Little France Crescent
University of Edinburgh
Edinburgh
United Kingdom
EH16 4TJ
+44 (0)131 242 6556/7
A.J.Simpson@ed.ac.uk

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 tolerablility, 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/01nrxwf90

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?
Results article	results	15/08/2013		Yes	No