

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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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/07/2011

Eligibility**Key inclusion criteria**

Healthy male volunteers aged 18 - 40 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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

United Kingdom

Scotland

Study participating centre

Room C2.12, MRC CIR

Edinburgh

United Kingdom

EH16 4TJ

Sponsor information

Organisation

University of Edinburgh (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

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