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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

Registration date
05/08/2009

Overall study status
Completed

Last Edited
05/02/2014

Condition category
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

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Additional identifiers

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)

Primary study design
Interventional

Study design
Single centre double-blind randomised controlled trial

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 tolerablility, 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
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Sponsor information

Organisation
University of Edinburgh (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

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