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Evaluation and control of lung inflammation assessed with positron emission tomography (PET) scanning in emphysema

Submission date 22/10/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/10/2008	**Overall study status** Completed	
Last Edited 04/03/2013	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Rob Stockley

Contact details
Lung Investigation Unit
First Floor
Nuffield House
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
030547

Study information

Scientific Title
Evaluation of the relative severity of pulmonary neutrophilic inflammation and therapeutic modification with intravenous prolastin by means of 18 fluoro-2-deoxyglucose (18FDG) positron emission tomography (PET)/computerised tomography (CT) scanning in subjects with usual chronic obstructive pulmonary disease (COPD) and alpha 1-antitrypsin deficiency

Acronym
ECLIPSE-AATD

Study objectives
18 fluoro-2-deoxyglucose (18FDG) positron emission tomography (PET)/computerised tomography (CT) scanning will enable non-invasive in vivo assessment of global neutrophilic inflammation in the lungs that relates to recognised biomarkers. It is anticipated that the level of lung inflammation will be highest in subjects with alpha 1-antitrypsin deficiency and lowest in healthy controls. Furthermore, it is anticipated that, following a 12-week treatment period of alpha 1-antitrypsin augmentation with intravenous (IV) prolastin, there will be a reduction in pulmonary inflammation that will be quantifiable with reference to subjects with usual chronic obstructive pulmonary disease (COPD) and healthy controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Hammersmith and Queen Charlotte's and Chelsea REC on 08/08/2008 (ref: 08/H0707/46).

Study design
Interventional single-arm trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details provided in the Interventions field to request a patient information sheet.

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD), emphysema, alpha 1-antitrypsin deficiency

Interventions
This is a proof of principle study. Study patients will acts as own controls by comparison between pre- and post-treatment measurements, and inter-group comparisons. Only those patients with alpha 1-antitrypsin deficiency will be treated with intravenous infusion of prolastin at a dose of 60 mg/kg per week for 12 consecutive weeks.

Please use the following contact details to request a patient information sheet:
Dr Anita Pye
Lung Investigation Unit
First Floor, Nuffield House
Queen Elizabeth Hospital
Edgbaston B15 2TH
Birmingham
United Kingdom
Tel +44 (0)121 697 8256
Email: anita.pye@uhb.nhs.uk

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prolastin

Primary outcome measure
Quantitative PET/CT using Patlak plots of uptake of 18FDG by lung tissue as a surrogate measure of pulmonary neutrophilic inflammation.

Primary and secondary outcome measures will be compared between groups at baseline. Only those patients with alpha 1-antitrypsin deficiency will be treated with prolastin, and comparison will be made between baseline and end of treatment values, within one week of treatment completion.

Secondary outcome measures
1. Other biomarkers obtained from sputum, whole blood and plasma
2. Relationship between emphysema severity and neutrophilic inflammation by inter-individual and intra-individual comparisons

Primary and secondary outcome measures will be compared between groups at baseline. Only those patients with alpha 1-antitrypsin deficiency will be treated with prolastin, and comparison will be made between baseline and end of treatment values, within one week of treatment completion.

Overall study start date
01/11/2008

Completion date
01/02/2011

Eligibility

Key inclusion criteria
Healthy controls:
1. Healthy subjects
2. Both males and females, aged 50 - 70 years
3. Those who have never smoked regularly for more than 3 months
4. No evidence of lung disease
5. Forced expiratory volume in 1 second (FEV1) greater than 75% predicted, FEV1/forced vital capacity (FVC) greater than 70% predicted
6. No relevant medical or mental disorder
7. Able to give informed consent

COPD patients:
1. Emphysema with no other active lung disease
2. FEV1 less than 75% predicted, FEV1/FVC less than 70% predicted, carbon monoxide transfer coefficient (KCO) less than 80% predicted (or known emphysema on previous CT scan)
3. Fewer than two acute exacerbations in the previous 12 months and no recent exacerbations (within 2 months)
4. No other relvant medical or mental disorder
5. Able to give informed consent

Patients with alpha 1-antitrypsin deficiency:
1. PiZ phenotype
2. Emphysema with no other active lung disease
3. FEV1 less than 75% predicted, FEV1/FVC less than 70% predicted, KCO less than 80% predicted (or known emphysema on previous CT scan)
4. Fewer than two acute exacerbations in the previous 12 months and no recent exacerbations (within 2 months)
5. No other relvant medical or mental disorder
6. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/11/2008

Date of final enrolment

01/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lung Investigation Unit
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TH

Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.uk

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name

Department of Health (UK) - Technology Platform Grant

Funder Name
Talecris Biotherapeutics (USA)

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	01/12/2012		Yes	No