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In situ detection of lung inflammation in chronic obstructive pulmonary disease using 18-fluorodeoxyglucose and positron emission tomography

Submission date 02/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/08/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/08/2006	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2004HO0826/GSK SCO103387

Study information

Scientific Title

Study objectives
Positron Emission Tomography (PET) is a three-dimensional imaging technique that measures physiological effects including metabolism. 18-fluorodeoxyglucose (18FDG) uptake is a well-validated in vivo measure of tissue glucose metabolism using PET and has been extensively used to monitor the metabolic activity of cells in the brain and to detect tumours. Inflammatory cells utilise glucose as a source of energy during their activation. It is hypothesised that 18FDG uptake by inflammatory cells in the lung could be used as an in vivo measurement of both total and regional lung inflammation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease

Interventions
The study is an observational study, correlating FDG uptake with other parameters that monitor inflammation.

18FDG injection: The subject will receive an intravenous administration of 18FDG of 3 MBq/kg to a maximum of 300 MBq, followed by PET scanning for 90 min.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
18-fluorodeoxyglucose

Primary outcome(s)
1. 18FDG uptake in the total lung, right and left lung
2. 18FDG uptake in three pre-defined lung regions (central, intermediate and peripheral) using the computerised shell analysis

Key secondary outcome(s))
1. Sputum inflammatory cells - Total Cell Count (TCC), Differential Cell Counts (DCC) from induced sputum obtained after 21 minutes nebulised hypertonic saline
2. Spirometry: FEV1, FVC
3. Sputum 18F activity levels post-imaging (COPD only)

Completion date
02/01/2006

Eligibility

Key inclusion criteria
Inclusion Criteria for Chronic Obstructive Pulmonary Disease (COPD) subjects:
1. Male or Female
2. 40 to 75 years of age
3. COPD, defined as the forced expiratory volume in the first one second to the forced vital capacity of the lungs (FEV1/FVC) being less than 70% that is not fully reversible defined as an increase of less than 15% of predicted FEV1 after inhaling 200 ug salbutamol:
a. mild COPD (Stage I) defined as FEV1 more than 80%, pre-bronchodilator
b. moderate COPD (Stage II) defined as 50% less than FEV1 less than 80%, pre-bronchodilator
c. severe COPD (Stage III) defined as 30% less than FEV1 less than 50%, pre-bronchodilator
4. Current or ex-smokers with more than ten pack year history (i.e. equivalent to 20 cigarettes smoked per day for ten years)
5. Written informed consent

Inclusion Criteria for COPD subjects during an acute exacerbation:
1. Male or Female
2. 40 to 75 years of age
3. Current or ex-smokers with more than ten pack year history (i.e. equivalent to 20 cigarettes smoked per day for ten years)
4. Written informed consent
5. Moderate to severe COPD, defined as FEV1/FVC less than 70% that is not fully reversible defined as an increase of less than 15% of predicted FEV1 after inhaling 200 ug salbutamol:
a. moderate COPD (Stage II) defined as 50% less than FEV1 less than 80%, pre-bronchodilator
b. severe COPD (Stage III) defined as 30% less than FEV1 less than 50%, pre-bronchodilator
6. Acute exacerbation, defined as a worsening of the subject’s condition from the stable state and beyond normal day-to-day variation, which is acute in onset and necessitates a change in regular medication

The subject must have two or three of the following clinical findings:
1. Worsening dyspnea
2. New or increased sputum purulence
3. Increased sputum volume
or one of the above clinical findings plus at least one of the following:
1. Upper respiratory tract infection in the past five days
2. Fever without other apparent cause
3. Increased wheezing
4. Increased cough
5. 20% increase in respiratory rate or heart rate above baseline

Subjects with an acute exacerbation must be within the first two to three days post-presentation of symptoms to be enrolled in the study.

Inclusion Criteria for Healthy Volunteers:
1. Male or Female
2. 40 to 75 years of age
3. Non-smoker
4. Written informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Exclusion Criteria for COPD subjects:
1. Other respiratory disorders, including asthma
2. Atopy
3. Other significant disease(s) which may put the subjects at risk or may have influence on the study results
4. Regular use of oxygen therapy
5. Pulmonary exacerbation in the previous four weeks (excluding subjects recruited during an exacerbation of COPD)
6. Received oral prednisone in the previous four weeks
7. Received antibiotics in the previous four weeks
8. Pregnancy or breastfeeding. If in childbearing years, female subjects will be required to provide a negative urine pregnancy test and must be using an acceptable hormonal or barrier contraceptive method to be included in the study. She must be willing to continue to use this type of contraception for the duration of the study

Exclusion Criteria for Healthy Volunteers:
1. History of respiratory disorders, including asthma
2. Atopy
3. Other significant disease(s) which may put the subjects at risk or may have influence on the study results
4. Received oral prednisone in the previous four weeks
5. Respiratory infection or cold in previous four weeks
6. Received antibiotics in the previous four weeks
7. Pregnancy or breastfeeding. If in childbearing years, female subjects will be required to provide a negative urine pregnancy test and must be using an acceptable hormonal or barrier contraceptive method to be included in the study. She must be willing to continue to use this type of contraception for the duration of the study.

Date of first enrolment

02/01/2005

Date of final enrolment
02/01/2006

Locations

Countries of recruitment
Canada

Study participating centre
1200 Main St West
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Sponsor information

Organisation
GlaxoSmithKline (Canada)

ROR
https://ror.org/02zz8mw60

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (Ref No. SCO103387)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary