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A randomised parallel group trial to investigate the effect of seretide withdrawal in Chronic Obstructive Pulmonary Disease (COPD) using non-invasive biomarkers and physiological measurements

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/04/2011	Respiratory	

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
N0226156349

Study information

Scientific Title

Study objectives
To investigate the effect of withdrawal of inhaled seretide on airway inflammation and airflow limitation in Chronic Obstructive Pulmonary Disease (COPD) patients using non-invasive measurement methods and lung function tests.

Please note that this record was extensively updated on the 9th November 2007. Updates were performed to the ethics, inclusion criteria, interventions and secondary outcome measures, as some of this information was not provided in the original record. Where changes have been made, the update date (09/11/2007) has been mentioned. Also please note that previous to this update, the anticipated end date of this trial was 03/07/2006.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added on 09/11/2007: Ethics approval received from the Central Manchester Local Research Ethics Committee on 25/02/2005.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
1. Seretide withdrawal group (withdrawal of Seretide dose for six weeks)
2. Continuation group

Added on 09/11/2007:
Patients will undergo spirometry, impulse oscillometry, body plethysmography, exhaled breath condensate, exhaled nitric oxide, induced sputum and questionaires at two occasions 2 weeks apart prior to randomisation and then at 2 weekly intervals for 6 weeks.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Induced sputum inflammatory cell counts

Key secondary outcome(s))
Added on 09/11/2007:
1. Exhaled breath condensate pH
2. Exhaled breath condensate Leukotriene B4, 8-isoprostane and other metabolites
3. Exhaled breath condensate and serum metabolite profiling by mass spectrometry
4. Exhaled nitric oxide in parts per billion (at 50 mls/sec, Caw, Calvin and Diffusing Capacity)
5. Induced sputum messenger Ribonucleic Acid (RNA) and protein for inflammatory mediators (e.g., Interleukin-8 [IL-8], Interleukin-6 [IL-6])
6. Sputum and blood gene expression (e.g., glucocorticoid receptor)
7. FEV1, Maximal Expiratory Flow (MEF), FVC (measured by spirometry)
8. Total Lung Capacity (TLC), Residual Volume (RV), Functional Residual Capacity (FRC), Inspiratory Capacity (IC), specific airways conductance (sGaw), airway flow resistance (Raw) (measured by body plethysmography)
9. Resonant Frequency (RF), Respiratory resistance at 5 Hz (R5), reactance at 5 Hz (X5) (measured by impulse oscillometry)

Completion date
31/07/2007

Eligibility

Key inclusion criteria
12 in withdrawal group and 12 in continuation group, patients aged 40 - 75 years

Added on 09/11/2007:
1. Males or females aged 40 - 75 years inclusive
2. Ex smokers or current smokers with a cigarette smoking history of pack years (1 pack-year = 20 cigarettes smoked per day for 1 year or the equivalent)
3. Subjects with Forced Expiratory Volume in one second (FEV1) 50 - 80% of predicted normal for height, age and sex at screening visit
4. Subjects with FEV1/Forced Vital Capacity (FVC) ratio less than 70% at screening visit
5. Patients taking inhaled seretide or combined fluticasone/salmeterol at a dose of 200 - 1000 µg fluticasone and 50 - 100 µg serevent per day
6. Subjects on a stable dose of all COPD treatment over the 4 weeks prior to starting the study
7. Subjects capable of providing signed written consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Subjects taking regular oral leukotriene receptor antagonists, oral cortiscosteroids, inhaled nasal corticosteroids, oral theophylline or inhaled tiotropium for 4 weeks prior to the study start
2. Subjects having one or more exacerbations of COPD in the past 12 months requiring treatment with oral corticosteroids
3. Subjects who have had a previous admission for exacerbation of COPD requiring non-invasive or endo-tracheal intubation or admission to the Intensive Care Unit (ICU)
4. History of asthma or significant atopy/rhinitis (requiring medication)
5. Subjects with uncontrolled angina, myocardial infarction within the last 12 months or congestive cardiac failure
6. Subjects with other significant pulmonary, cardiovascular, neurological, hepatic, renal, endocrine or haematological diseases
7. Female subjects who intend to become pregnant
8. Subjects who have experienced cold or flu-like symptoms or a respiratory infection within 4 weeks of the study start
9. Subjects who have received an investigational drug within 30 days or within 5 drug half-lives of the drug
10. Subjects with a history (or suspected history) of alcohol misuse or any other recreational substance abuse

Date of first enrolment
01/03/2005

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medicines Evaluation Unit
Manchester
United Kingdom
M23 9GP

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type
Government

Funder Name
South Manchester University Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

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	01/11/2009		Yes	No