

# 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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/04/2011	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr David Singh

**Contact details**  
Medicines Evaluation Unit  
Ledson Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9GP  
+44 (0)161 291 2672  
dsingh@meu.org.uk

## 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.

## Primary study design

Interventional

## Study design

Randomised controlled trial

## 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 questionnaires 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 corticosteroids, 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?
<a href="#">Results article</a>	results	01/11/2009		Yes	No