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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
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
05/04/2011

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0226156349

Study information

Scientific Title

Study hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
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 measure
Induced sputum inflammatory cell counts

Secondary outcome measures
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)

Overall study start date
01/03/2005

Overall study end date
31/07/2007

Eligibility

Participant 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

Age group
Adult

Sex
Both

Target number of participants
24

Participant 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

Recruitment start date
01/03/2005

Recruitment end date
31/07/2007

Locations

Countries of recruitment

England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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	01/11/2009		Yes	No