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Small particle steroid study

Submission date 21/12/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/01/2013	**Overall study status** Completed	
Last Edited 28/07/2015	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
The small airways (that carry air in and out of the lungs) have become increasingly important in asthma. We now have non-invasive tests of small airways function at our disposition, as well as inhaled drugs (containing smaller aerosol particles) targeting asthma at the level of the small airways. The aim of this study was to assess whether inhaled medications targeting the small airways offer any benefit over regular asthma drugs in terms of lung function (and more specifically small airways function) and asthma control. In addition the study will provide useful information about the inflammatory and structural alterations in the small airways.

Who can participate?
Non-smoking asthma patients, both male and female, over 18 years old on inhaled corticosteroids ("controller" drugs for asthma) and with abnormalities in the small airways can participate. Pregnant women were excluded from the study.

What does the study involve?
The study involved two patient groups: during a 15 week period the first group was treated with inhaled asthma medications targeting the small airways, whereas patients in the second group remained on regular asthma drugs. Lung function tests were performed before starting and after 3, 9 and 15 weeks. At each of those time point patients were also asked to fill out a short questionnaire (5 minutes) about their asthma. Each of the four study visits took approximately 1 hour. The asthma treatment was not interrupted throughout the entire study.

What are the possible benefits and risks of participating?
Study medication will be provided without any cost. No additional side effects are expected from the study medication, other than those related to the regular asthma treatment patients are already on. There are no risks associated with the lung function testing.

Where is the study run from?
The study took place in the UZ Brussel's (university hospital) outpatient clinic.

When is the study starting and how long is it expected to run for?
The study started in September 2009 and ran until August 2012.

Who is funding the study?
This study was funded by UCB Pharma.

Who is the main contact?
Dr Shane Hanon
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Small particle steroid study: a randomized double blind double dummy study

Study objectives
The residual lung function abnormalities in the small airways of the conductive and acinar lung zone could be smaller with the ultrafine anti-inflammatory aerosol [beclomethasone dipropionate (HFA-BDP); QVAR)] than with a regular anti-inflammatory aerosol [budesonide (DPI-BUD); Pulmicort TH)] in asthma patients with pre-existing small airways dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of UZ Brussel, 02/04/2009, ref: 2009/043, B.U.N. B14320096121

Study design
Randomized double-blind double-dummy study

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma / Small airways

Interventions
After a 3-week run-in on DPI-BUD patients are randomized to either arm 1 (DPI- BUD switched to BDP-HFA from wk 4 to wk 15) or to arm 2 (remaining on DPI-BUD)

The intervention takes 15 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Qvar (beclomethasone dipropionate), Pulmicort (Budesonide)

Primary outcome(s)
Change in Sacin (Multiple Breath Nitrogen Washout test). Sacin is a measure of ventilation heterogeneity in the acinar lung zone. Sacin increases with increasing heterogeneity. Measured at baseline and after 3, 9 and 15 weeks.

Key secondary outcome(s))
1. Alveolar and bronchial exhaled NO
2. Lung function parameters
3. Asthma control test (ACT) score
Measured at baseline and after 3, 9 and 15 weeks.

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. Well-established, stable asthma patients on inhaled corticosteroids
2. Age >18 years, male/female
3. Elevated baseline Sacin (>0.12 L-1)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Smoking history (> 10 packyears) or current smokers
2. Pregnant women

Date of first enrolment
01/09/2009

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
Belgium

Study participating centre
Laarbeeklaan 101
Brussels
Belgium
1090

Sponsor information

Organisation
University Hospital Brussels (Universitair Ziekenhuis Brussel [UZ Brussel]) (Belgium)

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Industry

Funder Name
UCB Pharma Brussels (Belgium) - Research grant

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	01/11/2014		Yes	No