

# Nebulizer trial: evaluation of the influence of particle size of aerosolized adenosine 5'-monophosphate on bronchial responsiveness in patients with asthma and the effects of treatment with ciclesonide versus fluticasone

<b>Submission date</b> 21/07/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/04/2019	<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**  
Prof D.S. Postma

**Contact details**  
University Medical Center Groningen (UMCG)  
Department of Internal Medicine  
Lung Diseases T3.260  
P.O. Box 30.001  
Groningen  
Netherlands  
9700 RB  
+31 (0)50 3614934  
d.s.postma@int.umcg.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

ClinicalTrials.gov number  
NCT00306163

**Secondary identifying numbers**  
BY9010/NL101

## **Study information**

**Scientific Title**

Nebulizer trial: evaluation of the influence of particle size of aerosolized adenosine 5'-monophosphate on bronchial responsiveness in patients with asthma and the effects of treatment with ciclesonide versus fluticasone

**Study objectives**

The aim of this study is to compare the responsiveness of lower airways in adult patients with stable asthma after treatment with ciclesonide and fluticasone propionate. Treatment medication will be administered as follows: ciclesonide will be inhaled once daily at one dose level, fluticasone propionate will be inhaled twice daily at one dose level. The study duration consists of a baseline period (five weeks) and a treatment period (five weeks). The study will provide further data on safety and tolerability of ciclesonide.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Interventional treatment randomised double-blind active-control parallel assignment

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Asthma

**Interventions**

Drug: Ciclesonide

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Ciclesonide, fluticasone propionate

**Primary outcome measure**

PC20 (AMP) (Posttreatment compared to baseline).

**Secondary outcome measures**

1.  $\Delta$  (Forced Vital Capacity [FVC]/Slow Vital Capacity [SVC]) at PC20 (AMP).
2. Safety and tolerability.

**Overall study start date**

01/05/2006

**Completion date**

01/01/2008

**Eligibility****Key inclusion criteria**

Main inclusion criteria:

1. History of bronchial asthma
2. Forced Expiratory Volume in once second (FEV1) more than 1.20 L
3. Positive skin prick test
4. Not more than 500 mcg/day fluticasone propionate or equivalent for at least 28 days prior to baseline visit

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

**Main exclusion criteria:**

1. Clinically relevant abnormal laboratory values
2. Concomitant severe diseases, diseases expected to interfere with the outcome of the study and diseases which are contra-indications for the use of inhaled steroids
3. Chronic Obstructive Pulmonary Disease (COPD) and /or other relevant lung diseases
4. One asthma exacerbation within two months or more than three exacerbations within the last year prior to baseline visit
5. Current smokers or ex-smokers with more than ten pack years, or having smoked within one year prior to baseline visit
6. Positive response to saline challenge at baseline visits
7. Positive bronchial hyperresponsiveness

**Date of first enrolment**

01/05/2006

**Date of final enrolment**

01/01/2008

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Center Groningen (UMCG)

Groningen

Netherlands

9700 RB

## **Sponsor information**

**Organisation**

Altana Pharma B.V. (The Netherlands)

**Sponsor details**

Dr. A.M. van Horssen

P.O. Box 31

Hoofddorp

Netherlands

2130 AA

**Sponsor type**

Industry

**ROR**

## Funder(s)

### Funder type

Industry

### Funder Name

Altana Pharma B.V. (The Netherlands)

## 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?
<a href="#">Basic results</a>				No	No
<a href="#">Results article</a>	results	01/03/2011	11/04/2019	Yes	No