

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

Submission date 21/07/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/07/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/04/2019	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00306163

Protocol serial number

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

Primary study design

Interventional

Study design

Interventional treatment randomised double-blind active-control parallel assignment

Study type(s)

Treatment

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(s)

PC20 (AMP) (Posttreatment compared to baseline).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/00ycncb81>

Funder(s)

Funder type

Industry

Funder Name

Altana Pharma B.V. (The Netherlands)

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	01/03/2011	11/04/2019	Yes	No
Basic results				No	No

