ISRCTN37115189 https://doi.org/10.1186/ISRCTN37115189

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 [X] 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

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. Δ (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

https://ror.org/00ycncb81

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?
Basic results				No	No
Results article	results	01/03/2011	11/04/2019	Yes	No