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Efficacy of Broncho-Vaxom® in allergic rhinitis

Submission date 29/05/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/06/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/08/2012	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BV-2007/03

Study information

Scientific Title
Efficacy of Broncho-Vaxom® in allergic rhinitis: A randomized, double-blind, placebo-controlled phase IIa study

Study objectives
Efficacy of Broncho-Vaxom® in preventing symptoms of allergic rhinitis as induced by a nasal provocation test with grass-pollen.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Committee of Clinical Research (Commission d'Ethique de la Recherche clinique), 07.05.2007, ref: 126/07

Primary study design
Interventional

Study design
Monocentric randomised placebo-controlled double-blind parallel group comparison phase IIa study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Seasonal allergic rhinitis

Interventions
Subjects were randomly assigned in an equal ratio to one of the two treatment arms. A stratified randomization was performed according to the outcome of the NPT screening (1st stratum threshold level ≤ 1000 SQ/ml: high sensitive subjects, 2nd stratum-threshold level >1000 SQ/ml: low sensitive subjects).

The dosage regimen was one capsule per day of Broncho-Vaxom® (1 capsule of 7 mg in the morning on an empty stomach) or placebo starting at least 7 days after the nasal provocation test (NPT) screening. The study period was a 30-days treatment period with a second NPT occurring one day before the end of treatment and a final visit with collection of nasal samples on the last day.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
1. The primary efficacy endpoint was defined as a difference in combined clinical thresholds to allergen nasal provocation test of at least one allergen dose level. The nasal reaction threshold (combined threshold) was reached when at least 2 of the 3 following clinical criteria were fulfilled:
1.1. Five or more sneezes in the first 10 minutes after the challenge, an increase from baseline value (obtained after diluent challenge) of at least 0.5 g of nasal secretions 10 minutes after the challenge, and a decrease from baseline values ≥40% in PNIF and/or ≥ 30% in MCA 10 minutes after the challenge.

at baseline (V1), treatment start(V2) , 29 days (V3) and 30 days (V4)

Key secondary outcome(s)

1. Objective symptom ratings
2. Subjective symptom ratings by means of a visual analogue scale (VAS)
3. Early and late allergic phase markers (from nasal secretions)

at baseline (V1), treatment start(V2) , 29 days (V3) and 30 days (V4)

Completion date
29/01/2008

Eligibility

Key inclusion criteria
1. Subjects must be 18 to 40 years of age, of either sex and any ethnic origin
2. Subjects must have at least a 2 year history of grass pollen induced seasonal allergic rhinitis (documented or reported by the patient)
3. Subjects must have a positive skin prick test response (wheel diameter >3 mm) and/or specific IgE for grass pollen (>0.35 kU/L).
4. Subjects must have a nasal reaction threshold of 10, 000 or less standardized quality units (SQs)/mL grass pollen, performed at the inclusion visit
5. Subjects must be free of any clinically significant disease, other than seasonal allergic rhinitis, which could 6. 6. 6. Subjects must have given written informed consent and must be able to adhere to dose, visits schedule and meet study requirements
7. In females of childbearing potential, the urine pregnancy test must be negative before performing the screening 8. Non-sterile or premenopausal female subjects must be using a medically accepted method of birth control, that is, oral contraceptive, hormonal implant, medically prescribed IUD, or depot injectable during the entire study. A female subject who was not of childbearing potential must have a medical record of being surgically sterile (for example, hysterectomy, and tubal ligation), or be at least 1 year postmenopausal

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subjects who have had an episode of allergic rhinitis in the last two weeks prior to screening
2. Subjects who have had an upper respiratory tract or sinus infection, that required antibiotherapy, or who have had a viral upper respiratory infection, in the last two weeks prior to screening
3. Subjects with asthma who require chronic use of inhaled or systemic corticosteroids (decrease

of peak flow > 20% of usual subject value)
4. Subjects with current seasonal (SAR) or perennial (PAR) allergic rhinitis
5. Subjects with known clinical allergic symptoms compatible with sensitization to tree pollens
6. Subjects with clinically significant nasal structural abnormalities (e.g. marked nasal septum deviation, major poliposis) that significantly interfere with nasal air flow
7. Subjects with current evidence of clinically significant haematopoietic, cardiovascular, hepatic, renal, neurologic, psychiatric, autoimmune disease, or other disease that preclude the subject's participation in the study
8. Subjects with a current history of frequent, clinically significant sinusitis or chronic purulent postnasal drip, or necessitating chronic intake of antibiotherapy
9. Subjects with non-specific nasal reaction (e.g. threshold reached with diluents alone at inclusion)
10. Subjects smoking more than 10 cigarettes/day and/or known to have severe alcohol intake and/or drug addiction
11. Subjects with intolerable symptoms that would make participating in the study unbearable
12. Subjects with a history of anaphylaxis and/or severe local reactions(s) to skin testing with allergens
13. Subjects with a history of hypersensitivity to the study drug
14. Subjects on immunotherapy or desensitization therapy
15. Subjects receiving any medication that might affect the test parameters (oral or topical antihistamines, steroids, antidepressants with antiallergical properties) within 2 weeks before study start (1 month for corticosteroids)

Date of first enrolment
08/08/2007

Date of final enrolment
29/01/2008

Locations

Countries of recruitment
Switzerland

Study participating centre
Division of Allergy and Immunology Centre Hospitalier Universitaire Vaudois Rue du Bugnon
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Sponsor information

Organisation
OM Pharma SA (Switzerland)

ROR

https://ror.org/0185z7g17

Funder(s)

Funder type
Industry

Funder Name
OM Pharma SA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration