

ALAP-1 for the attenuation of nasal provocation with histamine in seasonal allergic rhinitis: a randomised, double-blind, placebo-controlled, three-day dosing, cross-over study and dose finding one month cross-over study

Submission date 20/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/01/2008	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BB100A and BB100B

Study information

Scientific Title

Acronym

BB100A and BB100B

Study objectives

1. To evaluate the ability of ALAP-1 compared with placebo to reduce the signs and symptoms of allergic rhinitis (AR) in the presence of a nasal histamine challenge
2. To evaluate the efficacy of chronic dosing of ALAP-1 compared with placebo on reducing the symptoms of AR induced by nasal histamine challenge

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Copernicus Group Institutional Review Board (IRB) on the 19th September 2006 (ref: MED4-06-238).

Study design

Randomised double-blind placebo controlled crossover study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Seasonal allergic rhinitis

Interventions

ALAP-1 (herbal combination) versus placebo. ALAP-1 is an herbal combination formulated to prevent and reduce AR symptoms. This proprietary formula is a standardised blend of the following eleven botanical extracts: Cullen corylifolium (Psoralea fruit), Xanthium sibiricum (Xanthium fruit), Scutellaria baicalensis (Chinese skullcap root), Gardenia augusta (Gardenia fruit), Bupleurum chinense (Bupleurum root), Chrysanthemum x morifolium (Chrysanthemum

flower), Areca catechu (Areca husk), Schisandra spp. (Schisandra fruit), Ziziphus jujuba var. spinosa (Jujube seed), Nepeta tenuifolia (Schizonepeta aerial parts) and Plantago asiatica (Asian plantain seed).

Three-day study:

Subjects will consume three capsules of ALAP-1 (1350 mg) or placebo per day for two days and return to the research office on the third day for evaluation. Subjects undergo their baseline peak nasal inspiratory flow (PNIF) measurement and then consume four capsules of ALAP-1 (1800 mg) or placebo. Fifteen minutes later, the nasal histamine provocation is performed. Shortly after the histamine challenge, subjects consume an additional 4 capsules of ALAP-1 (1800 mg) or placebo. This dosing regimen simulates the method in which the formula would be used in practice: daily preventive doses during allergy season and a treatment dose in the event of direct exposure to an environmental allergen. Subjects then wash out for 1 week and are then enrolled into the opposite arm (active or placebo).

One month study:

Subjects will receive ALAP-1 or placebo for 4 weeks total. Initially, ALAP-1 (or placebo) is provided for 2 weeks at a high dose (1350 mg/day) and subjects undergo nasal histamine provocation and peak nasal inspiratory flow (PNIF) measurements. Then subjects are given ALAP-1 or placebo for 2 weeks at a low dose (900 mg/day). Subjects washout for 1 week and then are enrolled in the opposite arm.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

ALAP-1

Primary outcome measure

Peak nasal inspiratory flow meter, measured at 0, 10, 20, 30, 45 and 60 minutes post-histamine challenge on the study visit days.

Secondary outcome measures

Sneeze score, measured at 0, 10, 20, 30, 45 and 60 minutes post-histamine challenge on the study visit days.

Overall study start date

01/09/2006

Completion date

01/04/2007

Eligibility

Key inclusion criteria

1. Age 18 - 59 years, either sex
2. A history of seasonal allergic rhinitis

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Atrophic rhinitis
2. Rhinitis medicamentosa
3. Nasal polyps
4. Septal deviation
5. Active bacterial or viral sinusitis
6. Severe asthma
7. Peptic ulcer disease or active gastroesophageal reflux disease (GERD)
8. History of anaphylaxis to any allergen
9. Pregnancy
10. Active bacterial or viral rhinitis
11. Nasal surgery within the last eight weeks

Date of first enrolment

01/09/2006

Date of final enrolment

01/04/2007

Locations**Countries of recruitment**

United States of America

Study participating centre

18250 Roscoe Blvd.

Northridge

United States of America

91325

Sponsor information

Organisation

Radix Bioscience (USA)

Sponsor details

4436 Reeves Road
Ojai
United States of America
93023

Sponsor type

Industry

Website

<http://www.radixbioresearch.com/>

ROR

<https://ror.org/024hp8310>

Funder(s)**Funder type**

Industry

Funder Name

Radix Bioscience (USA)

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