ISRCTN83077547 https://doi.org/10.1186/ISRCTN83077547

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	[ ] Prospectively registered [ ] Protocol
Registration date 25/01/2008	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 25/01/2008	**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

Contact name
Dr Jay Udani

Contact details
18250 Roscoe Blvd.
Suite 240
Northridge
United States of America
91325

Additional identifiers

Protocol serial number
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).

Primary study design
Interventional

Study design
Randomised double-blind placebo controlled crossover study.

Study type(s)
Treatment

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

Key secondary outcome(s)
Sneeze score, measured at 0, 10, 20, 30, 45 and 60 minutes post-histamine challenge on the study visit days.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/024hp8310

Funder(s)

Funder type
Industry

Funder Name
Radix Bioscience (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration