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	Recruitment status	Prospectively registered
20/12/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/01/2008	Completed	Results
Last Edited	Condition category	Individual participant data
25/01/2008	Respiratory	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).

Study design

Randomised double-blind placebo controlled crossover study.

Primary study design

Interventional

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 summaryNot provided at time of registration