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Comparing the effect of two Ayurveda drugs on the treatment of allergic rhinitis

Submission date	**Recruitment status**	[X] Prospectively registered
18/04/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/08/2020	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Allergic rhinitis is an immune response of the nasal mucosa (lining of the nasal cavities) to airborne allergens and involves nasal congestion, watery nasal discharge, itching of the nose and sneezing. Allergic rhinitis is commonly defined as seasonal or perennial, depending upon whether symptoms occur at defined yearly intervals or throughout the year, respectively. Allergic rhinitis is not life threatening, but it is an annoying and disturbing disease for the patient due to its chronicity and aggravation when exposed to allergic agents. Furthermore allergic rhinitis is a considerable cause of widespread morbidity, medical treatment costs, reduced work productivity and lost school days. The symptoms of allergic rhinitis may significantly affect a patient's quality of life and can be associated with conditions such as fatigue, headache, cognitive impairment and sleep disturbances. Appropriate management of allergic rhinitis is an important component in the effective management of coexisting or complicated respiratory conditions such as asthma, sinusitis and sleep apnea. In this context, various complementary and alternative medicine treatments have been used for this condition in clinical practice. The Ayurveda system of medicine is the most common complementary medicine system in Sri Lanka. The aim of this study is to find out whether the use of two preparations (decoction and its freeze dried powder) over a period of 4 weeks is able to cure the symptoms of allergic rhinitis.

Who can participate?
Male and female patients aged 18 to 65 with allergic rhinitis

What does the study involve?
Participants are randomly allocated to receive either one of two Ayurveda treatments (traditional herbal decoction or a sachet containing freeze dried ingredients of herbal decoction) or the antihistamine loratidine for 4 weeks. Nasal symptoms are assessed at the start of the study, after four weeks of treatment, and after one month and two months of follow up.

What were the possible benefits and risks of participating?
The participants receive information and advice from a specialized medical team. In addition their participation may help to develop an Ayurveda drug treatment for allergic rhinitis.

Where is the study run from?
National Ayurveda Teaching Hospital (Sri Lanka)

When is the study starting and how long is it expected to run for?
January 2019 to May 2021

Who is funding the study?
University Grants Commission (Sri Lanka)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2016/Mphil-PhD/029

Study information

Scientific Title
Development of an Ayurvedic pharmaceutical preparation for allergic rhinitis and evaluation of its safety and efficacy

Acronym
AyudrugAR

Study objectives
Freeze dried powder of Tamalakyadi decoction will have similar efficacy and safety in treating patients with allergic rhinitis compared to the traditional decoction and antihistamines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/01/2019, Ethics Review Committee (Institute of Indigenous Medicine, University of Colombo, Rajagiriya, Sri Lanka; Tel: +94 (0)112692395; Email: ethicsreviewiim@gmail.com), ref: ERC 18/76

Primary study design
Interventional

Study design
Three-arm open-label non-inferiority randomized control clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Allergic rhinitis

Interventions
This will be a three-arm open-label non-inferiority randomized control trial in patients with allergic rhinitis. Consecutive consenting sample method will be followed to select participants of the arms for the study. A blocked design will be used, using an online statistical computing web programming to generate the randomization schedule (research randomizer https://www.randomizer.org). Eligible subjects will be randomly assigned to Arm I, Arm II and Arm III to receive herbal decoction, freeze-dried powder of herbal decoction and antihistamine for 28 days.

The patients of Arm I will be treated with herbal decoction (Tamalakyadi decoction), 120 ml twice a day after meals. Arm II patients will be treated with 6 g of freeze-dried powder of herbal decoction. The powder should be dissolved in 240 ml of hot water and should take 120 ml twice a day after meals. The patients of Arm III will receive antihistamine (loratidine 10 mg) at night taken with 240 ml of water. Patients belong to three arms have to visit the clinic weekly.

Total Nasal Symptom Score (TNSS) and IgE level of patients will be the primary efficacy endpoints. The mean difference in TNSS and IgE level will be compared between the three arms as the primary endpoints at the end of 28 days. The TNSS will be again analyzed after 1 month and 2 months of treatment at follow-up visits.

Mean score of daytime nasal symptoms, nighttime nasal symptom, non-nasal symptoms and Health-Related Quality of Life score will be used as secondary endpoints in the clinical trial. These symptom scores will be analyzed by using the information mentioned in rhinitis diary card of the patient. This diary cards will be collected weekly at the clinic.

Follow up – patients will be assessed after 1 month and 2 months at the clinic without a drug intervention.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Herbal decoction of Tamalakyadi decoction, freeze-dried powder of Tamalakyadi decoction, antihistamine (loratidine)

Primary outcome(s)
1. Nasal symptoms (watery rhinorrhea, sneezing, nasal obstruction, nasal itching) measured using the Total Nasal Symptom Score (TNSS) of allergic rhinitis patients at baseline and the end of intervention (after four weeks, after one month of follow up and two months of follow up)
2. Serum Immunoglobulin E level measured using chemiluminesent enzyme immunoassay (EIA) at baseline and after intervention

Key secondary outcome(s)
1. Mean score of daytime nasal symptom score
2. Mean score of nighttime nasal symptom score
3. Mean score of non-nasal symptoms
Patient self-rated symptom scores (daily rhinitis diary card) and allergic rhinitis grading symptoms collected on a weekly basis during the assessment period. The measurement of symptoms on a 4-point rating scale with the following definition will be used:
• 0 = absent symptoms (no sign/symptom evident)
• 1 = mild symptoms (sign/symptom clearly present, but minimal awareness; easily tolerated)
• 2 = moderate symptoms (definite awareness of sign/symptom that is bothersome but tolerable)
• 3 = severe symptoms (sign/symptom that is hard to tolerate; causes interference with activities of daily living and/or sleeping)
4. Health-related quality of life measured using HRQoL questionnaire (Valero et al, 2009 & 2013) at baseline and end of intervention (after four weeks, one month of follow up and two months of follow up)

Completion date
01/05/2021

Eligibility

Key inclusion criteria
1. Age 18-65 years at the time of enrollment, of either sex
2. No known systemic disorders
3. Newly diagnosed allergic rhinitis patients on Ayurvedic treatment
4. No history of drug allergy
5. Non-pregnant and non-breastfeeding
6. Have given written informed consent to participate in this study
7. Total Nasal Symptom Score (TNSS) more than 6

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria

1. Patients with deviated nasal septum/nasal polyps/nasal growth/adenoids/asthma
2. Patients with impaired liver and kidney functions, anaemia, and unstable cardiovascular conditions or cerebrovascular conditions
3. Currently or previously treated for any malignancy
4. Patients on steroid therapy
5. Already on treatment with herbal decoction or antihistamines
6. Pregnant or lactating mothers
7. Illiterate patients without a literate relative/guardian who can explain the procedures and maintain the patient diary

Date of first enrolment
30/05/2019

Date of final enrolment
30/05/2021

Locations

Countries of recruitment
Sri Lanka

Study participating centre
National Ayurveda Teaching Hospital
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Sponsor information

Organisation
University of Colombo

ROR
https://ror.org/02phn5242

Funder(s)

Funder type
Government

Funder Name

University Grants Commission - Sri Lanka

Alternative Name(s)
UGC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sri Lanka

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jeevani Dahanayake (jeevanimd@iim.cmb.ac.lk). Study participant data sheets will not include contact or identifying details. Study data entry and study management systems used by clinical sites will be secured and password protected. At the end of the study, all study databases will be de-identified and archived. Availability of raw data of the study is based on the above conditions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/01/2020	04/08/2020	Yes	No