Evaluation of Comparative Efficacy of Polyherbal Steam Inhalation versus Dhoopana (Polyherbal nasal fumigation) in Children with Pratishyaya (Rhinitis): A Randomized Controlled Clinical Trial

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Abstract

Background: Rhinitis is a condition characterized by inflammation of the nasal mucosa. It causes obstruction and congestion in the nasal cavity. Clinically, it resembles with Pratishyaya (Rhinitis) in Ayurveda which is caused by accumulation and downward movement of the Tridoshas (three elements named Vata, Pitta and Kapha) in the nasal cavity. Rhinitis is one of the most common diseases among children. There is no role of antibiotics in rhinitis. Nasal decongestants also not found effective in its proper management. In Ayurveda, Nasal fumigation (Dhoopana) is mentioned in the treatment protocol of Pratishyaya. But there is no any previous study found regarding its efficacy. Efficacy of the herbs Tulsi, Vasa, Nirgundi and Nilgiri is already proven as steam inhalation in respiratory tract infections. So, in this study Dhoopana (Nasal fumigation) of a polyherbal formulation containing Tulsi, Nirgundi, Vasa and Nilgiri will be compared with the steam inhalation containing Arka of Tulsi, Nirgundi, Vasa and Nilgiri in Pratishyaya in children.

Objective: Evaluation of the Efficacy of Polyherbal Steam Inhalation as a standard control against Polyherbal Nasal Fumigation (Dhoopana) in children lying in age group 7-14 years with Rhinitis (Pratishyaya): -A Randomized Controlled Clinical Trial.

Methods: After doing drug analysis, a total of 84 participants fulfilling the inclusion criteria will be selected and are distributed in two groups having 42 each. In group I (Intervention group) Polyherbal nasal fumigation (Dhoopana) in group C (Control group), Polyherbal steam inhalation will be given twice daily till 7 days. Assessment will be done on day 3rd, 5th, 7th and after the intervention; follow up will be taken on 7th, 14th day and 28th day.

Results: Results will be drawn from the observations of subjective and objective parameters.

Conclusions: Conclusion of the study will be drawn based on statistical data calculated from the collected data. Clinical Trial: CTRI No. - CTRI/2023/03/050876 (clinical trial registry India)
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Evaluation of Comparative Efficacy of Polyherbal Steam Inhalation versus *Dhoopana* (Polyherbal nasal fumigation) in Children with *Pratishyaya* (Rhinitis): A Randomized Controlled Clinical Trial

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Abstract

Background: Rhinitis is a condition characterized by inflammation of the nasal mucosa. It causes obstruction and congestion in the nasal cavity. Clinically, it resembles with *Pratishyaya* (Rhinitis) in Ayurveda which is caused by accumulation and downward movement of the *Tridoshas* (three elements named *Vata*, *Pitta* and *Kapha*) in the nasal cavity. Rhinitis is one of the most common diseases among children. There is no role of antibiotics in rhinitis. Nasal decongestants also not found effective in its proper management. In Ayurveda, Nasal fumigation (*Dhoopana*) is mentioned in the treatment protocol of *Pratishyaya*. But there is no any previous study found regarding its efficacy. Efficacy of the herbs *Tulsi*, *Vasa*, *Nirgundi* and *Nilgiri* is already proven as steam inhalation in respiratory tract infections. So, in this study *Dhoopana* (Nasal fumigation) of a polyherbal formulation containing *Tulsi*, *Nirgundi*, *Vasa* and *Nilgiri* will be compared with the steam inhalation containing *Arka* of *Tulsi, Nirgundi, Vasa* and *Nilgiri* in *Pratishyaya* in children. **Aim and Objectives**: Evaluation of the Efficacy of Polyherbal Steam Inhalation as a standard control against Polyherbal Nasal Fumigation (*Dhoopana*) in children lying in age group 7-14 years with Rhinitis (*Pratishyaya*): -A Randomized Controlled Clinical Trial. **Methodology**: After doing drug analysis, a total of 84 participants fulfilling the inclusion criteria will be selected and are distributed in two groups having 42 each. In group I (Intervention group) Polyherbal nasal fumigation (*Dhoopana*) in group C (Control group), Polyherbal steam inhalation will be given twice daily till 7 days. Assessment will be done on day 3rd, 5th, 7th and after the intervention; follow up will be taken on 7th, 14th day and 28th day. **Results:** Results will be drawn from the

observations of subjective and objective parameters. **Conclusion:** Conclusion of the study will be drawn based on statistical data calculated from the collected data.

Key Words: *Pratishyaya* (Rhinitis), *Dhoopana* (Nasal Fumigation), Steam Inhalation, Polyherbal, *Vasa*, *Nirgundi*, *Nilgiri*, *Tulsi*, Children, Sneezing, Nasal cavity.

Introduction

Rhinitis is defined as the inflammation of nasal mucosa due to any infection, allergy or injury. Symptoms of Rhinitis are Sneezing, discharge from nose, obstruction in nasal cavity, irritation in the nasal cavity, body ache, feverish sensation and headache. [1] As per Ayurveda, clinical picture of rhinitis is seen in the disease *Pratishyaya*. It is one among *Nasagata Roga* (Nasal disorders) in which *Kaphadi Tri Doshas* are continuously eliminated through the nose. These vitiated *Doshas* get accumulated in the head and their further movement towards the nose causes *Pratishyaya*. [2] According to Acharya Charaka, Definition of *Pratishyaya* is "*Pratikshnam shyayatiitipratishyaya*" means continuous outward movement of *Vata, Pitta and Kapha doshas* from nostrils is *Pratishyaya.* The prevalence of non-allergic rhinitis is about 40%. [3] The prevalence of allergic rhinitis in India was reported "11.3% in children aged 6-7 years and 24.4 % in children aged 13-14 years". [4]

Acharya Videha explained clinical presentation of *Pratisyaya* as Excessive secretions from nasal cavity and eyes, fever, generalised weakness with severe headache. [5] *Pratishyaya* is classified into 5 types as *Vataja*, *Pittaja*, *Kaphaja*, *Sannipataja* and *Raktaja Pratishyaya*. [6,7] Nasal mucosa has rich blood supply, stimulation of sympathetic nervous system causes vasoconstriction which further result in shrinkage of nasal mucosa on the other side, stimulation of parasympathetic system is responsible for excessive secretion from the nasal mucosa along with dilatation of local vessels. Emotional disturbance also plays a significant role as autonomic nervous system supply of nasal mucosa is under the control of hypothalamus. [3] If no any treatment is given at early stage it may get complicated and further lead to other co-morbid conditions like chronic rhinitis, cough, or breathing difficulty with debility. [8] There is no use of Antibiotics in acute rhinitis. [9] Antihistamine–decongestants are frequently used in cough and cold. But in some studies, these were not found effective in the management of rhinitis. [10] There is limited data regarding safety of Pseudoephedrine and phenylephrine in rhinitis. [11] As per Ayurveda, various oral medications are available for its management. But it is difficult to administer ayurvedic medicines orally to children. So, present study is planned to find an effective way to manage acute stage of rhinitis which could be administered locally in the nasal cavity. Various Ayurveda interventions are mentioned in Ayurveda classics as protocol for the management of

Pratishyaya out of which *Dhoopana* is one of the interventions, could effectively manage the disease. In this mode, various herbs are made into a stick known as *Varti* and its fumes are used for local fumigation of the affected area. It can be considered as an ayurvedic therapy that delivers the medicines directly into the airways which provide relief and protection to the local regions. [12]

In *Pratishyaya* treatment should be aimed to relieve the *Avarodha* (obstruction) created by the *Dosha*. Drugs having *Ushna* (hot) and *Tikshna* (pungent) properties are indicated in *Dhoopana*. Efficacy of *Tulsi*, *Vasa*, *Nirgundi* and *Nilgiri* is already proven as steam inhalation in respiratory tract infections. [13] So, in this study *Dhoopana* (Nasal fumigation) of a polyherbal formulation containing *Tulsi*, *Nirgundi*, *Vasa* and *Nilgiri* will be compared with the steam inhalation containing Arka of *Tulsi*, *Nirgundi*, *Vasa* and *Nilgiri* in *Pratishyaya* in children.

Need for the study:

Kashyapa Samhita is mainly devoted to Kaumarbhritya branch (Ayurvedic Paediatrics) of Ashtanga Ayurveda and *Dhoopana* is described in the treatment protocol of *Pratishyaya*. [14] There are many studies regarding efficacy of oral medication in *Pratishyaya* but there is no any previous study available regarding efficacy of local fumigation with medicated fumes in *Pratishyaya* (Rhinitis) in children. Steam inhalation has a known soothing effect over nasal mucosa in rhinitis. Herbal steam inhalation is more effective as compare to plain water steam inhalation [15], but still steam inhalation is quite difficult to administer in children. So, this study is planned to compare the effect of polyherbal steam inhalation with polyherbal fumigation in children suffering from *Pratishyaya* (Rhinitis).

The rationale of the study:

- The disease *Pratishyaya* (Rhinitis) is very common in Pediatric population, many medicines are available for its management but no any standardized ayurvedic therapy is available which can be given locally in nostrils in its acute stage. So, this study is planned to work upon acute rhinitis.
- Local fumigation and steam inhalation are simple and fast effective as compare to oral medication.
- Herbs chosen for Nasal Fumigation (*Dhoopana*) are justified as, in previous studies the herbs, *Tulsi*, *Nirgundi*, *Vasa* and *Nilgiri* were found effective for steam inhalation in reducing local inflammation in nostrils. So, these drugs are justified for the study.

Aim

To study the efficacy of Polyherbal steam inhalation versus *Dhoopana* (Polyherbal nasal fumigation) in children with *Pratishyaya* (Rhinitis).

Primary objectives

1. To determine the efficacy of *Dhoopana* (Polyherbal nasal fumigation) in reducing sign and symptoms of *Pratishyaya* (Rhinitis) over that of Polyherbal steam inhalation.
2. Can be studied the duration of alleviation of TNSS (Total Nasal Symptom Score).
3. To determine the efficacy of *Dhoopana* (Polyherbal nasal fumigation) in reduction of nasal obstruction in Modified cold spatula test.

Secondary objectives

1. Can be studied the prevalence of *Pratishyaya*, origin, causative factors, viral/bacterial/allergies etc.
2. Analysis of association between *Prakriti* and prevalence of *Pratishyaya* (Rhinitis) in children.

Trial design

Randomized reference controlled open label equivalence clinical study.

Methodology

Study setting - The patients will be selected from *Kaumarabhritya* OPD and IPD of Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (H) and from periphery. A total of 84 patients will be recruited for the study. Randomly they will be divided into 2 groups. Patients after initial screening will be subjected to randomization and will be included in two groups; Group C (Control group of Polyherbal steam inhalation) and Group I (Intervention group of Polyherbal nasal fumigation).

All the baseline parameters will be recorded at the start of the study. The patients will undergo treatment for 7 days for both groups. All the parameters will be recorded at the 3rd, 5th and 7th day.

Guidelines – used the SPIRIT Guidelines for the study.

Case definition – Patients suffering from Rhinitis (*Pratishyaya*) in the age group of 7 to 14 years.

Sampling procedure- Simple randomization using computer generated random number.

Type of Study- Interventional study.

Study Design- Randomized reference controlled open label equivalence clinical study. Detail is shown as flow chart in Fig.no.1.

Inclusion Criteria

1. Infant and children whose parents are giving written consent for enrolling their child in the study.
2. Patients of either sex aged between 7 to 14 years.
3. Patients suffering from common cold, presenting with features of *Pratishyaya* (Rhinitis) for 7-10days.

Exclusion Criteria

1. Patients suffering from common cold for more than 10days.
2. Patients with Chronic Allergic Rhinitis, *Dushta Pratishyaya, Raktaja Pratishyaya* and *Sannipataja Pratishyaya,* Infectious diseases like T.B.
3. Patients suffering from Cleft Palate, DNS, and Nasal Polyps.
4. History of hypersensitivity to the trial drug or any of its ingredients.

Details of drug preparation:

Dhoomvarti (Polyherbal stick) for nasal fumigation and *Arka* (for steam inhalation) from *Vasa, Nirgundi, Nilgiri* and *Tulsi* leaves will be prepared as per the classical methods and standard protocol in Mahatma Gandhi Ayurveda College and Hospital, Wardha Rasashala and will be analyzed in pharmaceutical laboratory.

Intervention modification – Any adverse effect during the treatment will be noted and will be informed to the ethical committee. The patients will be taken care of for the adverse effect. If participants want to drop-off will be mentioned with the reason for discontinuing the treatment.

Outcomes- To compare the efficacy of Polyherbal Nasal Fumigation (*Dhoopana*) and Polyherbal Steam Inhalation on Rhinitis (*Pratishyaya*) with criteria like subjective and objective parameters.

Subjective criteria- Sign and Symptoms of *Pratishyaya* (Rhinitis) by using TNSS (Total Nasal Symptom Score) illustrated in Table.no.

Objective Criteria- Modified Cold Spatula Test.

Participant timeline: Timeline is mentioned in the Gannt chart (Fig.no.2).

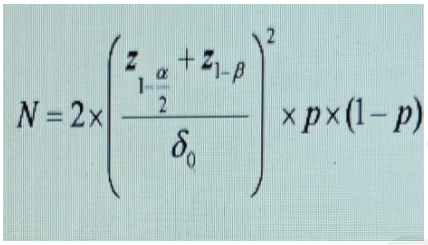
Recruitment

The patients will be selected from *Kaumarabhritya* OPD and IPD of Mahatma Gandhi

Ayurveda College, Hospital & Research Centre, Salod (H) and from periphery. A total of 84 patients will be recruited for the study.

Sample size

The minimum sample size is determined by a formula for equivalence



$$N = 2 \times \left(\frac{z_{1-\frac{\alpha}{2}} + z_{1-\beta}}{\delta_0} \right)^2 \times p \times (1-p)$$

Where:

δ_0 : margin that is clinically acceptable, p: Response rate of standard treatment group, α: Significance level and $1-\beta$: Power**.** Forgetting an estimator for sample size n, we assumed that p=0.7 and $\delta = 0.344$.

Then for a fixed level of significant $\alpha = 0.05$, and power $1 - \beta = 0.90$ the estimated sample size n = 37.258 If the drop~~out~~ rate d is 10%, final sample size N is obtained as $N =$ That is, N= 41.47 this is then rounded to 42. Hence, the number of samples needed per group is 42.

Allocation sequence generation – computer-generated random numbers.

Allocation implementation – Participants will be enrolled, given an intervention, and given an allocation sequence by the researcher or the original author.

Data collection plan – Detail information is mentioned in Table no.3.

Data collection tools and process-

Ayurveda Samhitas
Modern texts
Online search- Pubmed, Google Scholar, etc.
Polyherbal *Dhoomvarti* prepared from the powder of *Vasa*, *Nirgundi*, *Nilgiri* and *Tulsi*
Polyherbal *Arka* Prepared from *Vasa, Nirgundi*, *Nilgiri* and *Tulsi*
Case record form
Patient information
Written and informed consent form

Drug collection/ authentication-The raw material for the drug will be purchased from a reliable source and will be authenticated and identified by the department of Dravyaguna and *Rasashastra* of M.G.A.C.H. and RC, Salod, Wardha.

Statistics outcome – After the study, data will be analyzed according to a suitable statistical test.

Data Analysis (statistical methods)- The collected data will be analyzed with the help of an

inferential statistical test.

Data monitoring: formal committee -

Ethical consideration -The study has got clearance from the I.E.C. of Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha with Ref. No. MGACHRC/IEC/JULY-2022/522, the committee will decide on the endpoint and oversee the trial as it progresses.

The researcher will assess any adverse event and will be reported to the ethics committee.

Consent – Consent from parents and assent from patients will be taken before conducting the trial in the local language while explaining every aspect of the study.

The personal information of the participants will be collected and kept confidential before, during, and after the trial. Physical data will be stored in a protected storage facility with only access to the researcher. Computerized data will be held in a password-protected hard drive with only access to the researcher.

Competing interests - No competing interests were disclosed

Dissemination - This protocol will be further published as a thesis to disseminate the study for Rhinitis (*Pratishyaya*). The study protocol provides a detailed overview of the study design, methodology, data collection procedures, data analysis plan, and ethical considerations. By disseminating this protocol, we hope to advance knowledge in the field and facilitate future research.

Underlying data - No data is associated with this article

Reporting guidelines - SPIRIT Guidelines were used for the study.

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