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A Study Protocol on The Efficacy of Fluticasone Versus Bharangi (*Clerodendrom Serratum Linn*) Arka (Aqueous Extract) Nasal Spray In Pratishyaya (Chronic Allergic Rhinitis) In Children

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ABSTRACT

The pervasiveness of Allergic rhinitis among children is high while comparing other inflammatory diseases. Even though it doesn't have a direct impact on their well-being, it is the villain of the piece interrupting their healthy growth. A closer look at school-going children reveals the fact that Allergic rhinitis is one of the most visible symptoms that disturbs their cycle of life. Fluticasone nasal spray considered as the Gold Standard in COPD (Chronic Obstructive Pulmonary Disease) is the first line treatment method usually prescribed in this ailment. The disease Pratishyaya mentioned in classical Ayurveda texts exhibits features analogous to Allergic rhinitis. Arkaprakasha, serves as the principal testament to the sanative value of Bharangi Arka in Pratishyaya. The Arka prepared from the root of Bharangi has pharmacological effects adequate to pacify the disease. This study plans to evaluate the equivalent efficacy of Bharangi Arka and Fluticasone in Allergic rhinitis. Both of the drugs are administered in the form of nasal sprays since they can be applied more conveniently and easily on the school going group. For the study, 84 children from the age group of 4-14 years with Pratishyaya is selected arbitrarily fulfilling the inclusion criteria and is categorized into two groups. The choice between the nasal sprays is be made by Double- blind method and the assessment is done based on TNSS (Total Nasal Symptom Scoring) within a duration of 28 days. If Bharangi Arka is found to have a fruitful effect, it could foster further research with revamped Ayurveda formulations

Keywords

Allergic rhinitis, Bharangi arka, Nasagata roga, Kashyapsamhita, Pratishyaya

Introduction

Allergic rhinitis is the most niggling inflammatory disease that bothers the children time and again. It requires special attention as it can hamper their normal growth both mentally and physically[1]. While considering the clinical picture, it is the most reiterative symptom making it a common reason to take medical care, moreover by comparing the features, it can be weighed almost equal to Pratishyaya in Ayurveda[2]. In our classics, Pratishyaya is elucidated as one among the Nasagatarogas[3]. Despite being mentioned under the latter, it affects our body as a whole and compromises the quality of life. Pratishyaya (Allergic rhinitis,) even being a ubiquitous neglected disease, seems to have the worst upshot on school going children impeding their daily routine[4]. The pronounced characteristics of Pratishyaya are Kshavathu (sneezing), Nasa Avarodha (nasal obstruction), NasaSrava (nasal discharge), Talu Ostha Shosha (dryness of throat, palate, and lips), Shankha Nistoda (pain at temporal region), Swaropaghata (hoarseness of voice), Shiro Gauravam (heaviness of head)., Gala, Ostha, Talu, Nasa and Netra Kandu (itching of throat, lips, palate, nose, and eyes)[5]. The aforesaid clinical presentations are just the tip of the iceberg. If not managed on time, the sequelae appear as Kasa(cough/tussis), Swasa, and Kshaya (depletion) piece by piece, sooner or later leading to death. The reappearing frequency of this disease can be attributed by a lower level of immunity in children or AsampurnaBala (Lack of strength and endurance of body) in other respects. Approaches to boost the child's immunity would ward off the recurrence and complications.

The treatment principles for Pratishyaya are spoken through SusrutaSamhita[6] and KashyapSamhita[7] as entirely separate chapters. The drugs which possess katu-tikta rasa, ushnaveerya, and katuvipaka help to mitigate the disease. Bharangi is one such drug and Arka Kalpana is laghu and sukshma in nature. This catalyses the desired effect[8]. The conjoint actions of Bharangi and Arka Kalpana are the grounds on which Bharangi Arka was picked for the study.

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The similarities in features helps to draw a parallel between Pratishyaya and Allergic rhinitis .In the physiological perspective, the shrinkage of the nasal mucosa and excessive secretions in Allergic rhinitis are engendered by the stimulation of sympathetic and para sympathetic systems accordingly[9].Allergic rhinitis is quite possibly the most widely recognized hypersensitive sickness around the world, influencing around 10-25% of the populace. About 20-30% of the Indian population experiences no less than one Allergic illness. As per the International Study of Asthma and sensitivities in Youth (ISSAC) stage 1 (1998), in India, nasal manifestations solely were exhibited in 12.5% and 18.6% of kids while hypersensitive rhino conjunctivitis affected 3.3% and 5.6% kids belonging to the 6-7 and 13-14 age brackets respectively.[10]

Literature Review

According to Amarkosha[11], the condition of continuous nasal discharge is called Pratishyaya. Pratishyaya is the most common disease in which the nasal mucus membrane gets inflamed.It is characterized by Kshavathu(Sneezing), Graanaoparodha(Nasalblock), Shirashoola(Headache),Aruchi(Anorexia),Nasasrava,Swarabhedha(Hoarseness fsound),Klama(Fatigue),Jwara(Fever),Granaviplava(Anosmia)[12].Allergic rhinitis is an inflammatory disorder of the nasal mucosa described by nasal blockage, rhinorrhea, and itching, and frequently joined by wheezing and conjunctival aggravation. It is a significant constan t sickness of youngsters in light of its high commonness, co-morbidities, and inconvenient impact on personal satisfaction in school execution [13]. In the present study, Bharangi Arka helps in pacifying the distorted Vata and Kapha dosha. Also, many phytochemical studies and pharmacological research have revealed the anti-inflammatory, anti-allergic, and anti-asthmatic effects of Bharangi apart from its bronchodilator activity[14]. Among different types of treatment, in the nasal medication conveyance, the Nasal Spray is by all accounts the most encouraging conveyance strategy for nearby and foundational infection treatment. Nasal deposition conduct is the most basic and important interaction for nasal spray, as it is linked to nasal mucociliary clearance. Pharmacotherapy and immunotherapy are the first line of treatment in managing allergic rhinitis. Depending on the condition, various intranasal corticosteroids are also administered in many cases. The significant benefit of Intranasal corticosteroid administration is that high concentrations of the medication, with a quick beginning of the action, can be conveyed directly into the respective organ so systemic impacts are kept away from or limited[15]. Fluticasone nasal spray is another effective corticosteroid, with improved action and a side-activated conveyance device. Since it has high potency and fewer systemic impacts, it is quite effective for Allergic rhinitis treatment[16].

Research gap summary

- In India, the complementary and alternative systems of medicine are significant in treating chronic, debilitating conditions. [Tabish S. A. (2008)][17]
- Though it provides temporary relief, it has failed to address the severity and type of Allergic rhinitis.
- Most of the conventional Nasal Sprays and Nasya medicines come in combination types which cause a headache, epistaxis, nasopharyngitis, pyrexia, pharyngolaryngeal pain, nasal ulceration, cough, back pain, etc. with high cost. [Pedro GiavinaBianchi (2008)][18]
- Ayurveda can thus be rationalized to provide a holistic, non-linear, and yet complex means of managing such Paediatric diseases. [Rioux J. (2012)][19]
- Antihistamines, Steroids, Leukotriene receptor antagonists, Chromones, Decongestant Nose drops, or combination nasal sprays are the recent advances of biomedicine in Allergic rhinitis. [InformedHealth.org][20]
- Ayurveda has a well-defined conceptual framework with a high translational value which can be rationalized from its philosophical framework. [Manohar P. R. (2016)][21]
- Shadbindu taila Nasya was found to have significant effectiveness over Allergic rhinitis [Gangaprasad 2016][22] and hence a similar route of administration i.e., Nasal Spray was chosen as nasal deposition conduct is the most basic and important interaction linked to nasal mucociliary clearance [Mingyue Gao (2020)][23]
- Long-term intensive therapies are not suitable for children. [Small, P. (2018)][24]
- Advanced research for fast-acting, safe, and effective means of Paediatric practice is necessary
- Bharangi Arka is a preparation that is capable of subsiding Pratishyaya by its deepana, kaphasamana, and vatanulomana, Vata & Kapha doshahar properties, anti -anti-inflammatory, anti-allergic, broncho-dilatory, and anti-asthmatic effects. [Manjunatha Adiga (2018)][25]

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- The use of Bharangi Arka for Nebulization in the treatment of Tamaka Swasa was shown to be successful in delivering the active components of the medicine straight to the target location with rapid action. So, a single formulation that can provide continual relief from symptoms if administered for a short period of time was chosen. [Thejaswini R. (2019)][26]

- The current protocol is also planned to assess the anti-allergic activity of the classical drug Bharangi Arka.

The rationale of the study

- Being the most common disease among school-going children, the choice of this disease in Kaumarabrithya is to be justified.
- In this study, the drug Bharangi (*Clerodendrom serratum Linn*) has been selected due to its potent anti-allergic, anti-asthmatic and anti-inflammatory, antioxidant properties due to the presence of icosahydropicenicacid, ursolic acid, saponins, steroids, flavonoids, phenolics, etc. Also, the single drug formulation, in its distilled form is used in treating Pratishyaya.
- Nasal drug delivery can be considered the most effective mean to enhance the bioavailability of the drug as it increases the retention time.

- Since Nasya (errhine therapy) is contraindicated in children and a method of noninvasive drug delivery is desirable, the use of a nasal spray can be found effective, and hence chosen.
- As the medicine is to be administered to children, the Nasal Spray is a simpler method.
- The use of a nasal spray can also be justified considering that it is cost-effective.

Research Question

Does Fluticasone Versus Bharangi Arka as a Nasal Spray has equivalent Efficacy in reducing the signs and symptoms of Pratishyaya (Chronic Allergic Rhinitis) in children in a double-blind Controlled equivalent clinical Study?

This study aims to find whether Fluticasone Versus Bharangi Arka as a Nasal Spray has equivalent Efficacy in reducing the signs and symptoms of Pratishyaya (Chronic Allergic rhinitis) in children with a double-blind Controlled equivalent clinical Study.

The objectives are :

1. To evaluate the Clinical Efficacy of Bharangi Arka and its Efficacy on AEC in the management of Pratishyaya (Chronic Allergic rhinitis).
2. To evaluate the Clinical Efficacy of Fluticasone and its Efficacy on AEC in the management of Pratishyaya (Chronic Allergic rhinitis)
3. To compare the Clinical Efficacy of both Fluticasone and Bharangi Arka in the management of Pratishyaya (Chronic Allergic rhinitis).

Methodology

Study Type: Interventional.

Study Design: Randomized double-blind, Standard Controlled Comparative Equivalence Clinical Study. A minimum of 84 diagnosed children of Pratishyaya fulfilling inclusion criteria will be randomly selected and divided into two groups.

Randomization Method of selection of comparator: Computer generated Random Number Table method will be used to avoid bias in the study. Blinding and allocation concealment: Double blinding by covering both Nasal Spray bottles with a thick cloth sticking and coding by a third person**.**

Study setting:

This experimental study is to be carried out in the Outpatient and Inpatient Departments of Kaumarabhritya, Mahatma Gandhi Ayurveda College and Hospital Ward.

Annals of R.S.C.B., ISSN: 1583-6258, Vol. 28, Issue 1, 2024, Pages. 61 - 71

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Sample size calculation:

The minimum sample size is determined by a formula,

$$n = 2\left(\frac{z_1-\frac{\alpha}{2}+z_1-\beta}{\delta_0}\right)^2 xpx(1-p)$$

Where,

$\boldsymbol{\delta_0}$: margin that is clinically acceptable

p: Response rate of standard treatment group

$\boldsymbol{\alpha}$: Significance level

$\mathbf{1-\beta}$: Power

For getting an estimator for sample size n, we assumed that p=0.7 and $\delta_0 = 3.44$. Then for a fixed level of significant $\alpha = 0.05$, and power $1 - \beta = 0.90$ the estimated sample size is, $n = 37.258$. If the dropout rate d is 10%, final sample size N is obtained as $N = \frac{n}{1-d}$. That is, N = 41.47.This is then rounded to 42. Hence, the numberof samples needed per group is 42.

Participants:

Written informed consent is to be collected from the parents of the children after giving them a clear picture about the research procedures.

Eligibility criteria：

Inclusion Criteria	Exclusion Criteria
Patients irrespective of gender, religion, and socioeconomic status	Patients with Acute Allergic rhinitis.
Age group between 4-14 years	Ptients with DushtaPratishyaya, RakthaPratishyaya and SannipatajaPratishyaya
Patients with Pratishyaya for more than 1 week or recurrent 3-6 episodes in a year (Chronic Allergic rhinitis).	Patients Infectious diseases like T.B.
Patients whose parents are ready to provide a written informed consent for their children to take part in the research.	Patients suffering from Cleft Palate, DNS, and Nasal Polyps

Ethical considerations:

Withdrawal criteria/stoppage rules: During the treatment period, if the condition of the patient gets worse, the case will be excluded and will be given conventional treatment and care.
Follow-up for subjects withdrawn: The excluded subjects are given appropriate management. Follow-up will be done till the symptoms subside at free of cost.
A description of the “stopping rules” or “discontinuation criteria” for individual subjects: The therapy shall be discontinued, and the subject exempted from the study in the following events:

- If subjects get affected with any other diseases which affect the study, during the treatment period.
- If the subjects have any personal issues to continue the therapy which is likely to affect the outcome of the study.

Procedure:

A total of 84 children belonging to the age group 4-14 years affected with Pratishyaya satisfying inclusion criteria will be selected and divided into Two groups such that each group will have 42 members. One of the groups will be given Fluticasone Nasal Spray and the other will be given Bharangi Arka Nasal Spray for 28 days. The drug for each group will be selected using double blinded method and named as Group M and Group N respectively based on the drugs administered. The

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assessments will be done on 1st, 7th ,14th,21st and 28th day depending on the criteria and the results in each group are compared to achieve the objectives proposed.

Details of number of subjects, medication, mode of administration and pattern of assessment:

	Group M	Group N
Subjects	42	42
Name and details of the medication	Fluticasone	Bharangi Arka
Dosage form	Spray one time in each nostril	Spray one time in each nostril
Duration	Twice daily, Morning & Evening	Twice daily, Morning & Evening
Assessment	1st day and every 7th ,14th,21st and 28th day	1st day and every 7th ,14th,21st and 28th day
Route / Mode of administration	Nostrils	Nostrils

Method of preparation of Bharangi Arka: Coarsely powdered Bharangi root is mixed with twice the quantity of water and kept in Shade. While the powder is soaked well, water equal to the powder is poured into the vessel. It is placed under the sun and in the shade for the next 8 days. This liquid is transferred to the distilled apparatus, cooked on low fire and Arka is collected.

Assessment Criteria

Subjective parameters will be graded 0,1,2 and 3 according to their severity and objective parameters will be tested before and after treatment and compared. Assessment will be done based on detailed performance and analysed statistically.

Assessment criteria

Subjective parameters	Objective parameters
TNSS (Total Nasal Symptom Score)	Total Leucocyte Count
Kasa	DC [Differential Count] TLC [Total Leukocyte Count]
Shirasoola	ESR [Erythrocyte Sedimentation Rate]
Aruchi	AEC [Absolute Eosinophil Count] Body temperature

Total Nasal Symptom Score (TNSS)

Symptom	Domain	Scale
Rhinorrhoea	No symptom	0
	Awareness but not troubled-mild	1

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	Troublesome but not interfering with normal daily activities or sleep – Moderate	2
	Interfering with normal daily activities or sleep- severe	3
Nasal itching	No symptom	0
	Awareness but not troubled-mild	1
	Troublesome but not interfering with normal daily activities or sleep – Moderate	2
	Interfering with normal daily activities or sleep- Severe	3
Nasal obstruction	No symptom	0
	Awareness but not troubled-mild	1
	Troublesome but not interfering with normal daily activities or sleep – Moderate	2
	Interfering with normal daily activities or sleep- Severe	3
Sneezing	No symptom	0
	Awareness but not troubled-mild	1
	Troublesome but not interfering with normal daily activities or sleep – Moderate	2
	Interfering with normal daily activities or sleep- Severe	3

Scoring for Kasa:

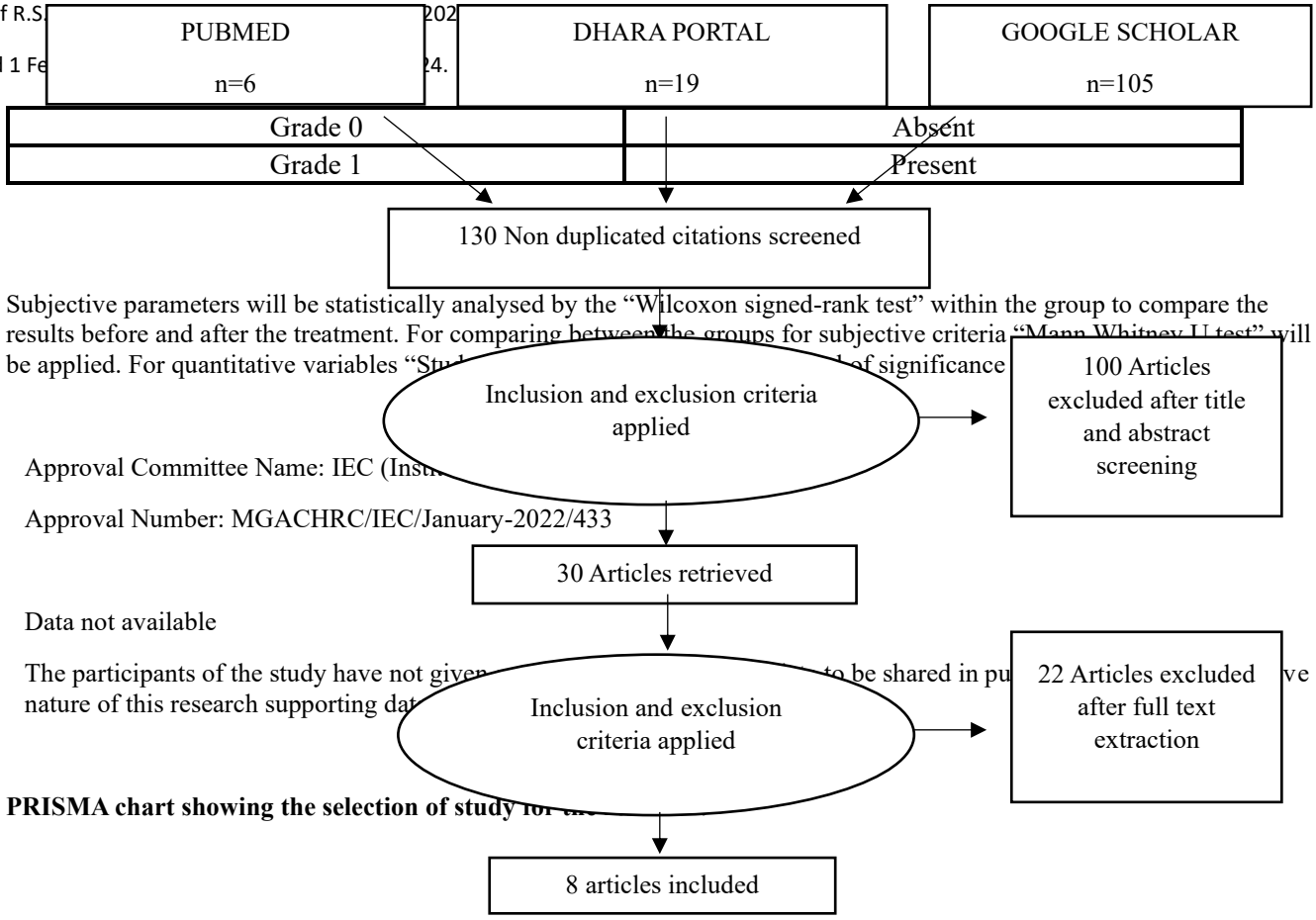
Grade 0	No cough
Grade 1	Occasional cough
Grade 2	Moderate cough
Grade 3	Continuous cough with throat and chest pain

Scoring for Shirasoola:

Grade 0	No headache
Grade 1	Occasional headache
Grade 2	Frequent headache
Grade 3	Continuous headache

Scoring for Aruchi:

Received 1 Fe 24.



Subjective parameters will be statistically analysed by the "Wilcoxon signed-rank test" within the group to compare the results before and after the treatment. For comparing between the groups for subjective criteria "Mann Whitney U test" will be applied. For quantitative variables "Stu of significance

Approval Committee Name: IEC (Insti

Approval Number: MGACHRC/IEC/January-2022/433

Data not available

The participants of the study have not give to be shared in pu ve nature of this research supporting dat

PRISMA chart showing the selection of study for th

Annals of R.S.C.B., ISSN: 1583-6258, Vol. 28, Issue 1, 2024, Pages. 61 - 71

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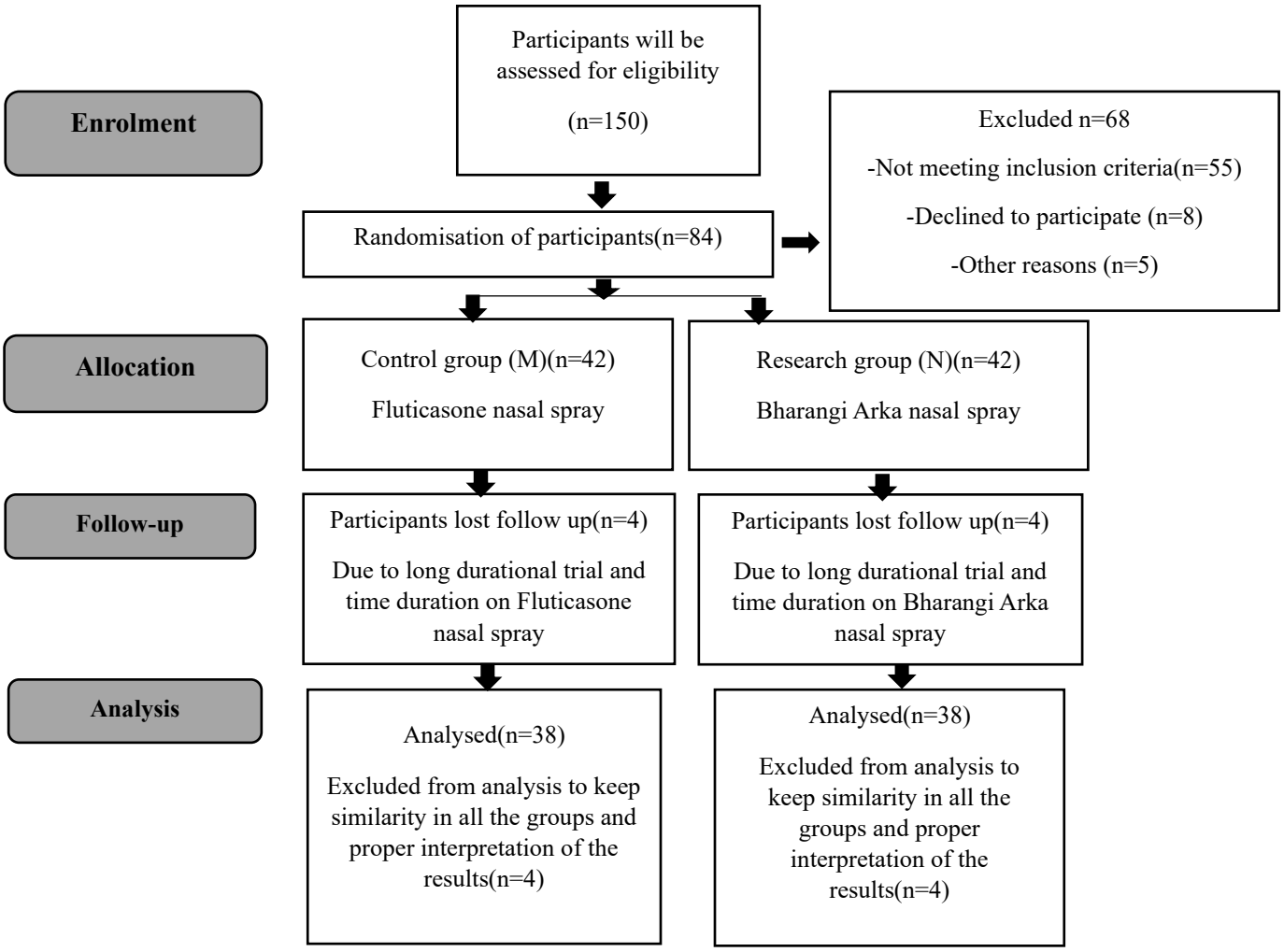
CONSORT chart displaying participant selection and progress:



GANTT chart illustrating the schedule of the research:

GANTT CHART												
Time line (Quarterly)	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Q11**	**Q12**
Title, Research question												
Synopsis												
Literature review												
Data collection												
Data analysis												
Dissertation writeup												
Dissertation submission												

Annals of R.S.C.B., ISSN: 1583-6258, Vol. 28, Issue 1, 2024, Pages. 61 - 71

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Competing interests:

No competent interests were disclosed.

Grant information:

The authors declared that no grants were involved in supporting this work.

Discussions:

Studies have been conducted on the internal administration of Bharangi Arka showing significant results in Pratishyaya. Even as a single drug formulation it could provide more opportunities to explore the field of Ayurveda in the treatment of Pratishyaya. A study using cost-effective Bharangi could be an initiation for developments in formulations involving more than one drug. Also, it can show how effective is Bharangi Arka Nasal Spray when we have Fluticasone Nasal Spray, the widely used remedy for Rhinitis on the other side.

Limitations and Future Studies

Publication plan

- To publish articles related to the Ayurvedic view of Pratishyaya (Chronic Allergic rhinitis).
- An article enumerating different treatment modalities in Ayurveda for Pratishyaya and their scope.
- An article reviewing the Bharangi Arka and standardization of the drug.
- A case report on the efficacy of Bharangi Arka in Pratishyaya (Chronic Allergic rhinitis).
- An article on Randomized Controlled Clinical Study on the Efficacy of Bharangi Arka and Fluticasone Nasal Spray in Pratishyaya (Chronic Allergic rhinitis) in Children
- Limitations can only be determined through proper analysis after the completion of the study.

Scope & future implications:

- Allergic rhinitis is one of the frequently troubling conditions especially in children, where more care is needed because it affects the normal growth and development of the children.
- The chronic nature of Allergic rhinitis and its association with other comorbid conditions like asthma, eczema, and even pneumonia has shown a significant negative impact on quality of life, school performance, and cognitive functioning in children which has influenced many parents to seek an alternative.
- Generally, people desire to get relief from their trouble in a minimum period. Though several medicines are available in every system of medicines for curing a single disease, there are always challenges for an effective and safe drug.
- As a result of such an exploration, the present preliminary research study is planned to know about the anti-allergic activity of the classical drug compound Bharangi Arka by administering it to children suffering from Pratishyaya. Bharangi Arka is a preparation that can subside Pratishyaya by its deepana, kaphasamana, and vatanulomana properties.

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