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Homoeopathic Treatment of Allergic Rhinitis: A Clinical Study Protocol

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ABSTRACT

Background: Allergic rhinitis is a common long-term condition in which the nose reacts to airborne allergens such as pollen, dust mites and animal dander. It causes sneezing, a runny or blocked nose and itching, and it affects sleep, school or work performance and quality of life. Conventional treatment relieves symptoms but does not always prevent them from returning, and many patients look for other options. Earlier homoeopathic studies have reported benefit, but it is still unclear which medicines work best in practice.

Aim: To assess the role of homoeopathic medicine in the management of allergic rhinitis.

Materials and methods: This is a prospective clinical study planned for 12 months at the outpatient department (OPD) and peripheral OPD of S. S. Agrawal Homoeopathic Medical College and General Hospital, Navsari. Thirty patients below 50 years of age, of either sex, with diagnosed allergic rhinitis will be selected by simple random sampling. People with advanced pathology or weakened immunity will be excluded. A detailed case will be taken for every patient, and an individualised homoeopathic medicine will be prescribed. Symptom severity will be recorded before and after treatment with the Nasal Allergic Rhinitis Scoring System (NARSS), which rates five symptoms from 0 to 3 for a total of 0–15. Outcomes will be classed as recovery, improvement, status quo or no improvement.

Expected outcome: The study is expected to show whether symptom scores fall after individualised homoeopathic treatment and to describe the medicines most often needed. The findings will help to plan larger controlled trials.

Keywords: Allergic rhinitis, Hay fever, Individualised homoeopathy, Nasal Allergic Rhinitis Scoring System, Clinical study protocol

1. INTRODUCTION

Allergic rhinitis is an allergic disease of the nose. It is marked by clear nasal discharge, a blocked nose, sneezing, nasal itching and a feeling of discharge running down the back of the throat [1,2]. It is caused by an over-reaction of the immune system to airborne allergens. The allergen is picked up by immune cells in the nose, T-helper 2 cells release chemical messengers such as interleukin-4, -5 and -13, and the body makes immunoglobulin E (IgE). IgE attaches to mast cells, which release histamine and other substances when the allergen returns, and these cause swelling of the lining of the nose, extra mucus and itching [3,4].

Allergic rhinitis is traditionally divided into seasonal and perennial forms, according to whether symptoms follow the pollen season or occur through the year. House dust mites, moulds, feathers and animal dander are the commonest causes of the perennial form, and pollens and moulds cause the seasonal form [3,5]. Current guidelines also describe the disease as intermittent or persistent, and as mild or moderate-to-severe, according to how long the symptoms last and how much they disturb sleep and daily activity [5,6]. The disease is also linked with other allergic conditions of the airway and skin, such as asthma, conjunctivitis, sinusitis and atopic dermatitis, which fits the idea of a single airway affected by one allergic process [3,4].

Allergic rhinitis is among the most common long-term conditions worldwide, and it is thought to be under-diagnosed and under-treated. Reports from India suggest that it has become more common over recent decades, but good community-based data, particularly from rural and semi-urban areas, are limited, so the true burden may be higher than reported [4,7]. Genetic susceptibility and environmental exposure both play a part, and a family history of allergy raises the chance of the disease [3,4]. Apart from nasal complaints, patients often have itchy and watery eyes, a dry cough, blocked ears and poor sleep, and the condition reduces school attendance, work output and quality of life.

Conventional treatment consists of avoiding allergens, antihistamines, nasal steroids and, in some patients, immunotherapy. These measures can control symptoms well, but symptoms often return when treatment stops, and some patients are troubled by side effects or prefer a different approach [5,6].

Homoeopathy treats the whole person and bases the choice of medicine on the totality of mental, general and local symptoms and on the underlying constitution, not on the diagnosis alone [8,9]. A number of homoeopathic medicines are described for hay fever and perennial rhinitis, including Allium cepa, Sabadilla, Arsenicum album, Natrum muriaticum, Pulsatilla, Euphrasia, Arundo and Dulcamara [10–12]. A randomised, placebo-controlled trial of

homoeopathy in perennial allergic rhinitis reported a benefit over placebo [13]. A prospective, open, non-comparative study of individualised treatment in seasonal allergic rhinitis reported improvement in symptoms and quality of life [14], and the design of a three-armed randomised trial in seasonal allergic rhinitis has also been published [15]. Despite this work, it remains unclear which medicines are most useful in routine practice. This study was designed to add clinical data from an Indian hospital setting.

2. AIM, OBJECTIVE AND HYPOTHESIS

Research question: Is homoeopathic medicine effective in the management of allergic rhinitis?

Aim and primary objective: To assess the role of homoeopathic medicine in the management of allergic rhinitis.

Hypothesis: Homoeopathic medicine is effective in the management of allergic rhinitis (alternative hypothesis). The null hypothesis is that it produces no change in symptoms.

3. MATERIALS AND METHODS

3.1 Study design and setting

This is a prospective clinical study. It will be done at the OPD and peripheral OPD of S. S. Agrawal Homoeopathic Medical College and General Hospital, Navsari.

3.2 Duration, sample size and sampling

The study will run for 12 months. Thirty patients will be selected by simple random sampling.

3.3 Eligibility criteria

Inclusion criteria

- Patients with diagnosed allergic rhinitis, of either sex, below 50 years of age.

Exclusion criteria

- Patients with advanced pathology.
- Immunocompromised patients.

3.4 Diagnosis

The diagnosis will be based on the typical history and examination, with sneezing, nasal discharge, nasal blockage, nasal itching and watery eyes as the main features [1,2]. Laboratory tests, such as allergy skin testing, specific IgE, total blood eosinophil count and routine blood tests, will be used where they are needed to support the diagnosis or to rule out other conditions [3].

3.5 Case-taking and prescribing

Written informed consent will be taken from each patient, or from a guardian in the case of a child. A specialised case proforma will be used to record the chief and associated complaints (with location, sensation, pathology, modalities and concomitants), personal, past and family history, physical generals, general, physical and systemic examination, investigations, life space, fundamental and dominant miasm, and susceptibility. The symptoms will be analysed, the totality and the repertorial totality will be formed, and the final medicine will be selected with the reasons recorded. Follow-up visits will be recorded on a remedy reaction evaluation form. Each patient will be studied individually, and the effect of the medicines will be reviewed at the end of the study.

3.6 Outcome assessment

The primary outcome is the reduction in the intensity of symptoms. The secondary outcome is the reduction in recurrence or in the frequency of symptoms. Intensity will be measured with the Nasal Allergic Rhinitis Scoring System (NARSS), which rates five symptoms from 0 (no symptoms) to 3 (severe symptoms):

NARSS item	**Score range**
Nasal congestion	0–3
Rhinorrhoea (nasal discharge)	0–3
Sneezing	0–3
Nasal itching	0–3
Postnasal drip	0–3
Total	**0–15**

A total of 0–5 is read as mild, 6–10 as moderate and 11–15 as severe allergic rhinitis.

The results in each patient will be classed as follows:

- **Recovery:** the main complaints are relieved or have disappeared completely, no new symptoms appear and the patient's wellbeing is restored.
- **Improvement:** significant relief of complaints.
- **Status quo:** no change in the symptoms even after an adequate period of observation, with no reaction to the medicine.
- **No improvement:** no change in the symptoms, together with new complaints.

3.7 Statistical analysis

Descriptive statistics will be used to describe the patients, and the NARSS scores before and after treatment will be compared with ANOVA or the Z test, as laid down in the approved protocol. A p-value below 0.05 will be taken as significant.

3.8 Ethical considerations

The proposal is reviewed by the Institutional Ethics Committee of the college, in line with national and institutional guidelines. Data will be collected ethically after informed consent. Participation is voluntary, a patient may withdraw at any time without giving a reason, and records will be kept confidential. [Insert ethics approval number and date.]

4. MEDICINES COMMONLY CONSIDERED

The following summary is drawn from standard materia medica sources [10–12] and is meant to show the range of medicines that may be needed.

- **Allium cepa:** profuse, watery and burning nasal discharge that makes the upper lip raw, with bland, watery eyes; better in the open air, worse in a warm room and in the evening.
- **Sabadilla:** spasmodic, violent sneezing with a watery, profuse discharge, red watery eyes and frontal headache; marked sensitivity to smells.
- **Arsenicum album:** thin, watery and burning discharge with a blocked-feeling nose and ineffective sneezing; worse in the open air and at night.
- **Natrum muriaticum:** sudden, violent sneezing with watery discharge like raw egg-white, and loss of smell and taste.
- **Pulsatilla:** thick, yellow-green discharge, a nose blocked on one side, a changeable picture, worse in a warm room and better in the open air.
- **Euphrasia:** profuse, burning watery eyes with a bland nasal discharge, worse in the evening.
- **Arundo:** itching of the palate, nose and eyes, with sneezing and loss of smell.
- **Dulcamara:** dry, blocked nose brought on by cold, damp weather.

Other medicines named in the protocol include Ambrosia, Galphimia, Histaminum, Graphites, Silicea, Kali bichromicum and Natrum sulphuricum.

5. EXPECTED OUTCOMES AND SIGNIFICANCE

The study is expected to show whether symptom scores fall in patients with allergic rhinitis who receive individualised homoeopathic treatment, and which medicines are most often indicated. These findings can guide clinicians and help in planning larger controlled trials.

6. LIMITATIONS

The design has limits that should be kept in mind when the results are read. There is no control or placebo group, so any improvement cannot be credited to the medicines alone, because symptoms of allergic rhinitis change with season and exposure, and the consultation and expectation may help. The sample of 30 is small, and it comes from one institution. The NARSS is a symptom score rated from the patient's report and the doctor's judgement, so it is subjective. The outcome definitions depend on clinical judgement and do not use a validated global scale. The study is of 12 months, which may be too short to follow seasonal variation and recurrence.

7. CONCLUSION

Allergic rhinitis is a common condition, and many patients seek treatment that deals with the person and not only the symptoms. Homoeopathy is widely used for this purpose, but the evidence for particular medicines in routine practice is limited. This protocol describes a structured clinical study that applies detailed case-taking and a simple symptom score to assess the role of individualised homoeopathic medicines in allergic rhinitis. The results will be reported when the study is complete.

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