Research Proposal

Effect of Shunthyadi Taila Nasya Versus Pippalayadi Taila Nasya Along With Chitraka Haritaki Systemically in the Management of Kshavathu (Allergic Rhinitis): A Research Protocol

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ABSTRACT

Background: Poor life style habituates such as physical inactivity, exposure to mist, wind, dust, sleep disruption increase are the factors responsible for allergic symptoms of the nose and its severity. Allergic rhinitis (AR) is a mild to moderate allergic disease which affects approximately 10% to 30% of the world population. Symptoms usually include runny nose, sneezing, nasal obstruction and nasal itching can vary from individual, with current treatment modality such as antihistamine, intranasal glucocorticoid treatment and immunotherapy which need longer period.

Need of the study: In classic the symptoms of AR are seen in nasa roga under kshavathu where it's get relief from symptoms and increase the immune system. Hence Shunthyadi taila and Pippalayadi taila nasal drop along with Chitraka Haritaki systemically in the management of Kshavathu.

Aim of the study: To compare the effect of nasya with Shunthyadi taila and chitraka Haritaki with pippalaydi taila and Chitraka Haritaki in management of Ksavathu (Allergic Rhinitis).

Materials and method: Methodology of the study is active control single blind superiority clinical trial. 196 patients of kshavathu will be treated by randomly dividing them into two, Group I having 98 patients will be subjected to Shunthyadi taila nasya and Chitraka Haritaki Systemically. Group II control having 98 patients will be subjected to Pippalayadi taila nasya and Chitraka Haritaki Systemically. The result will be draw from observation of the study after treatment.

Keywords: Acute Rhinitis, Nasya, Alternative therapy, Sneezing

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INTRODUCTION

Shalakya Tantra deals with diseases of organs situated above jatru (clavicle) and their treatment. Nasa is an jatrurdwa avayava. Hence disorder of nose and their treatment are included in Shalakya Tantra [1]. Allergic Rhinitis (AR) affects 10% to 30% people worldwide [2]. AR is one such disorder which rapidly increases these days, so it demands great concern [3]. Symptoms of AR usually include watery nasal discharge, continuous sneezing, nasal congestion and itching. The symptoms can vary from person, and patients may be in great pain during exacerbations [4]. The current treatment modality includes avoidance of the allergens, antihistamine, corticoid steroids therapy and immunized drugs [5].

In Ayurveda, the symptom sneezing is seen in vataja pratishyaya and ksavathu [6]. In vataja pratishyaya, along with sneezing, nasal blockage, thin nasal discharge, dryness in throat, lips and palate region, throbbing pain in temple region and hoarseness of voice are explained[7]. In some studies, allergic rhinitis is compared with dustapratishyaya but it is a condition manifested as complication of untreated pratishyaya. Symptoms are fever, difficulty in breathing, cough, pain in chest region, dryness in nose and if discharges present it will be mucopurulent blood stained discharge [8]. Ksavathu (sneezing) is a disease where in sneezing is the crucial feature. Ksavathu is of two types according to Acharya Dalhana. Agantuja ksavathu (external factors) is caused due external factors like irritants in the environment which lasts only for a brief period. Doshaja ksavathu (due to imbalance in the doshas) is chronic in origin caused due to imbalance in the doshas. The vitiated vata and kapha doshas gets lodged in the nose due to sroto-vaigunya caused by indulgence in the causative factors of nasa roga. The aggravated doshas settled in nasa vitiate the vital points i.e. the marmas and exhibits the symptom of the disease i.e. sneezing [9]. Due to paroxysmal sneezing there will be altered in nasal secretion leads to nasal blockage. In this chronic stage, the agni (digestive fire) is impaired and leads to accumulation large amount of Ama (unmetobolized waste which cannot be used by the body). With all these references, it is clear that allergic rhinitis better correlates with ksavathu than vataja pratishyaya. Considering the above matters, in this stage it is important to plan the treatment which addresses both the factors agni and elimination of the doshas. As allergic rhinitis is an IgE mediated immune response, it is also important to have an anti-allergic effect so as to make the patient symptom free for longer duration. In the study taken as control group pippalyadi taila and shunthyadi taila were the trial drug [10]. Pippalyadi taila is the drug of choice in the treatment of pratishyaya but shunthyadi taila

in ksavathu [11]. Hence, Shunthyadi taila nasya with Chitraka Haritaki has being selected for the study. chitraka hareetaki which is indicated in kasa, swasa, urah kshata, peenasa and also has added benefit of increasing the agni and vatanulomana, will be useful in anti- allergic effect which is very crucial in treating nasal allergy [12]. In previous studies the formulation are given in nasal drops only to reduce the symptoms which does not help in anti-allergic effect and also reduce the chronicity [13]. Present study will be done to evaluate and compare the effect of nasya with Shunthyadi taila and chitraka Haritaki with pippalaydi taila and Chitraka Haritaki in management of Ksavathu (Allergic Rhinitis).

Objectives

1. To evaluate the effect of nasya with Shunthyadi taila and chitraka haritaki in management of Kshavathu (Allergic Rhinitis).
2. To evaluate the effect of nasya with pippalyadi taila and Chitraka Haritaki in management of Kshavathu (Allergic Rhinitis).
3. To compare the effect of Shunthyadi taila nasya versus Pippalyadi taila nasya along with Chitraka Haritaki systemically in management of Kshavathu (Allergic Rhinitis).

Hypothesis

Null Hypothesis (primary hypothesis) H0: There is no significant effect of Shunthyadi thaila nasya vs Pippalyadi taila nasya and Chitraka Haritaki systemically on kshavathu (AR). There is significant difference in different Symptom of Kshavathu before treatment & follows up after e.g. 60th day of treatment is true and statement is accepted .

Alternative Hypothesis (secondary hypothesis) H1: There is significant effect Of Shunthyadi taila nasya vs Pippalyadi taila nasya and Chitraka Haritaki systemically on kshavathu (AR), there is significant difference in different Symptom of Kshavathu before treatment & follows up after e.g. 60th day of treatment is true and statement is accepted.

REVIEW OF LITERATURE

1. Clinical study of Haridra Khanda & Pippalyadi Taila Nasya on Pratishyaya (Allergic Rhinitis) was carried out by Dr. Chhaya bhakti in IPGTRA, Gujarat Ayurveda University, Jamnagar in 2009 [14]. Conclusion was given as combined group showed significant treatment outcome. No significant variation seen in haematological parameters. Finally concluded that IgE parameter was not included so further research is needed.
2. Clinical study of nasya taila with Shunthyadi and Triphaladi taila in vataja

pratishayaya (Allergic Rhinitis) was carried out by Dr. Hiremath V.R in BMK Ayurveda College, Karnatka in 2014 [15]. Conclusion was given group A had better result than group B. But shunthyadi taila nasya and chitraka haritaki will have combined anti-allergic effect and recurrence free.

3. Case study of Shadbindu Ghrita nasya in vataja pratishyaya(allergic rhinitis) was carried out by Dr. Swapna in SDM Ayurveda College, Karnatka in 2020 [16]. Conclusion was given shadbindu ghrita nasya were effective in complete sustained amelioration of the symptoms. But concluding that shunthyadi taila nasya and chitraka haritaki will effect in parameters like AEC, IgE

MATERIALS AND METHODS

Randomised control superiority trial, double arm with 98 patients in each group. Treatment Period is one month in which Marsha Nasya will be done for 7 Days and chitraka haritaki internally for 1 month will be given. Duration of the study is 2 years from March 2022 to 2024. Study sample will be selected from the patients attending the Shalakya tantra OPD of Mahatma Gandhi Ayurveda College & Hospital, Wardha. Also conducting medical camp in Urban area offices/School, pamphlets advertisement in Government hospital and ENT centre for the purpose of the study.

Ethics approval: ethics committee/institutional ethics committee (REC/IRB) approval MGACHRC/IEC/Sept. 2021/384 dated 8.10.2021

Consent: PI will obtain informed consent from the subject and it will maintain Confidentiality

Sample size

Random sampling method technique will be followed and type is active single blind superiority clinical trial CTRI/2022/02/040245 Registered on 11/02/2022.

From Bhakti C.et.al study effect of pippalyadi taila nasya and Haridra khanda in Vataja Pratishyaya (allergic Rhinitis) the sample size is calculated on

SD of sneezing (AT) in above study = 0.68 [17]

Formula $N= \frac{2S^2 [Z_{(1-\alpha)} + Z_{(1-\beta)}]^2}{(m_1-m_2)^2}$

Superiority clinical Trial

Determination of sample size:

n = required sample size

M_1 = mean test intervention = 2.73

M_2= mean of control intervention = 3.2

Standard deviation of M_1 = 0.68

Standard deviation of M_2 = 0.91 [18]

Pooled (S.D) = 0.68+ 0.91/2

S.D = 1.135

(1- α) = set level of confidence, usually 0.95 (95%)

(1-β) = set level of power of test, usually used value 0.8(80%)

Therefore Z (1- α) = 1.95

Z (1-β) = 0.84

$$N = \frac{2(1.135)^2 * (1.95 + 0.84)^2}{(2.73-3.2)^2}$$

$$\frac{2 * 1.29 * 7.61}{(-0.47)^2}$$

$$\frac{2*1.29*7.61}{0.221} = 89$$

Considering 10% drop out 89* 10/100= 8.9 = 9

Therefore total sample size required for the study = n +9 = 89+9 = 98 (in one group)

Inclusion criteria

1. Patients aged ≥19 years are included with following complaints are watery nasal discharge, paroxysmal sneezing, nasal blockage or two or more symptoms.
2. Those have given written informed consent are included.

Exclusion criteria

1. Presently taking medications or steroids and immune modulatory/ immunosuppression, those who cannot stop medication are excluded.
2. Patients with acute sinusitis and respiratory disorders who receive treatment currently.
2. Patient who have congenital defect or underwent surgery of the nose within previous months.
3. Patients with malignant tumour, pulmonary diseases, past history of asthma, DNS/ ethmoidal polyp/ adenoids are excluded [19].

Diagnosis will be done by assessing the Total Nasal Symptom Score TNSS; score is about 0-12 -assessed for sneezing, rhinorrhea, nasal congestion, nasal itching, evaluated with scale 0=None, 1=Mild, 2=Moderate, or 3=Severe. Detail anterior rhinos copy examination will be done and documented [20].

Study Groups

Group I: Shunthyadi taila nasya 8 bindu (4 ml) will be instilled in each nostril for 7 days in morning at empty stomach. Internally Chitraka haritaki 6gms twice a day for 1 month (1 karsha i.e. 12gms in divided dose). Follow up will be done on 45nd, 60th day

Group II: Pippalyadi Taila nasya 8 bindu (4 ml) will be instilled in each nostril for 7 days in morning at empty stomach. Internally Chitraka haritaki 6gms twice a day for 1 month (1 karsha i.e. 12gms in divided dose). Follow up will be done on 45nd, 60th day [Table-1].

Method of preparation of drugs

The drugs enlisted will be taken and prepared as per classical reference Astanga Hridyam. Drugs are Shunthi (Zingiber Officinale) ,Pippali (piper longum), Vidangam (Embelia

ribes), draksha (vitis vinifera), Kusta (saussurea lapa) each one pala are taken in vessel . Made into coarse powder (Kashaya choorna) and add sixteen parts of water then boiled and filtered the 1/4th part. One position of kashaya choorna will be taken to which 4 parts of tila taila (sesamum indicum) and sixteen parts prepared kashyam were mixed and then boiled till Sneha or Tila Taila only left behind. Shunthyadi Taila at Mrdu Paka will be prepared from GMP certified pharmacy are used for Nasya[21]. The same procedure is followed for Pippalaydi taila with the ingredients are pippali (piper longum). Sigru beeja (Moringa oleifera), vidanga (Embelia ribes) , marica (piper nigrum). The drugs enlisted in Chitaka Hareetaki avaleha will be prepared as per bhasajya ratnavali. Fine powder drugs are Chitraka (plumbago zeylanica), Amrita (Tinospora cordifolia), Dasamoola, Trikatu (Piper nigrum , piper longum, Zingiber officinale). Prepare kashyam with 400 phala of the Citrakamoola (plumbago indica), dwipanchamoola, amruta and one armana juice of dhatri (phyllanthus emblica) added with three dronas of water and reduce to 1/4th to make decoction. Jaggery100 phala and one adhaka pathya are added with decoction and process again. After settle to reduce heat finally add ½ prastha honey, 6 palas vyosa, trisugandha choorna , ½ palaksara are mixed to it and chitrakaharitaki lehya will be prepared [22].

RESULTS

Patient will be assessed by objective parameter such as IgE level, AEC (Absolute Eosinophil Count) on baseline and after treatment. Subjective parameters are Nasal Symptom Score (TNSS), questionnaire regarding quality of life, symptom score of AR will be assessed baseline and after treatment i.e. 45th and 60th days [23].

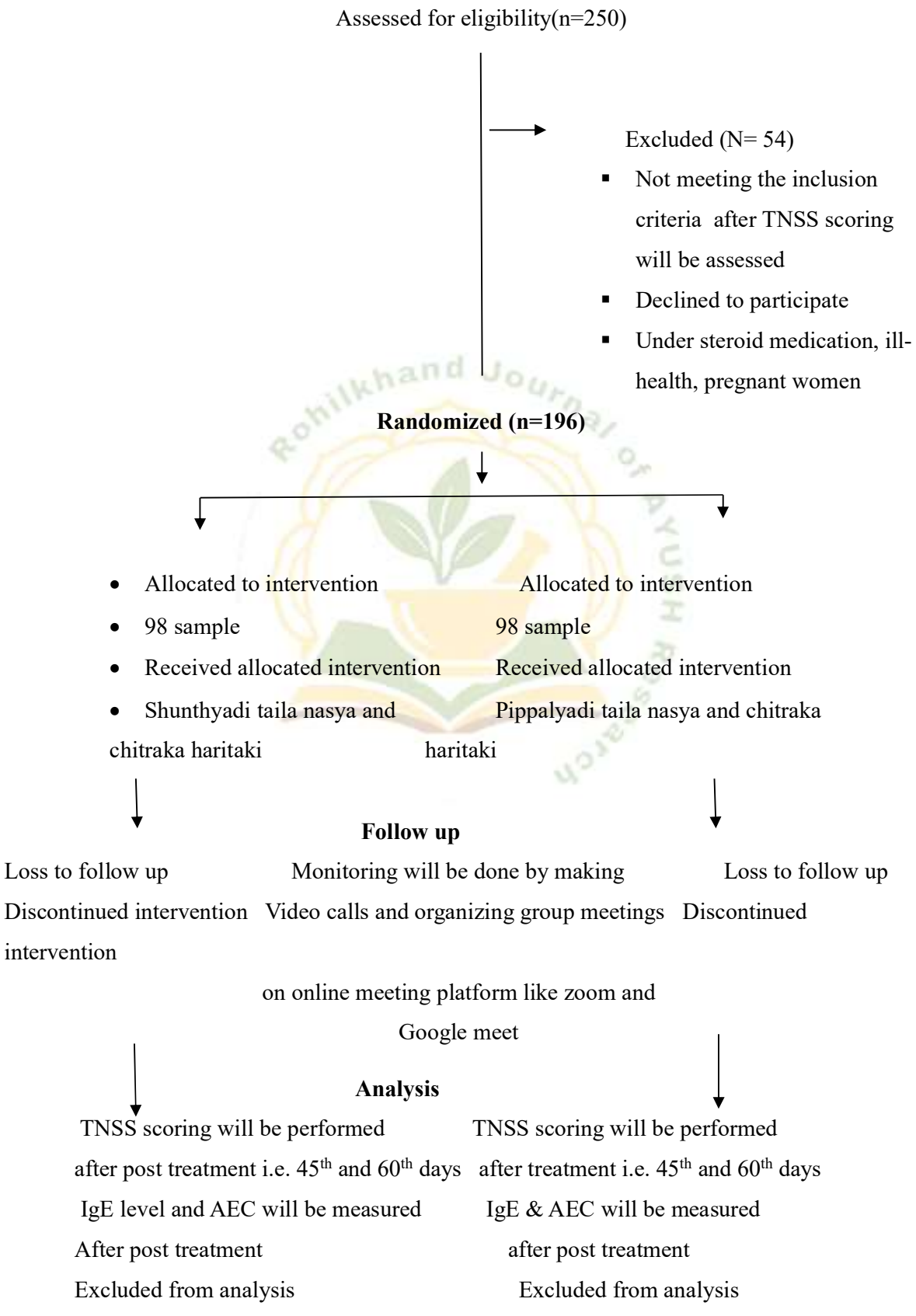
Gradation of Assessment criteria

Total Nasal Symptom Score (TNSS):

TNSS score is about 0-12 -assessed for sneezing, rhinorrhea, nasal congestion, nasal itching, evaluated with scale 0=None, 1=Mild, 2=Moderate, or 3=Severe. Allergic rhinitis symptom score

The assessment period will be done on weekly basis and symptoms score will be recorded. It is measured on rating scale with 4 points are 0 – no evident of symptoms, 1 to 3 are measured as mild (easy tolerable/minimal), moderate (definitely bothersome), severe symptoms (hard to tolerate the signs/symptoms, also causes interference with day today activities)

Timeline: Table 1



DISCUSSION AND CONCLUSION

Statistical analysis

The data will be analysed by using appropriate statistical methods SPSS 2.0 version. Assessment criteria will be statistically analyzed by applying suitable Z Test for within group and for between the groups Wilcoxon 'Mann Whitney U' Test will be applied. Level of significance will be taken at 5%.

1. To compare the results within the same group on different days on subjective and objective parameter Z test statistical method will be used.
2. To compare the results between the groups on subjective and objective parameter Wilcoxon Mann Whitney U Test statistical method will be used.

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