Evaluation of Efficacy and Safety of Peenisa Hair Oil in Peenisam (Allergic Rhinitis)

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Introduction

Recurrent infection remains a common presentation in ENT practice despite the decrease in frequency of pyogenic infections with new generation antimicrobials. It has been suggested that persistent or recurrent URT infections that do not respond to antibiotics should alert the doctor to a possible underlying immuno –deficiency(.Spickett GP, Chapel HM, (1998)).

Peenisam is a disorder in which there are episodes of nasal congestion, watery nasal discharge & sneezing. The Peenisam is attributed to various environmental allergens such as pollen grains , dust, climatic changes in terms of temperature, humidity, house dust, fungal spores & animal dander. Peenisam is characterized by clinical manifestation as watery nose, sneezing and nasal congestion due to the hypersensitivity of small airways.

Recent studies have demonstrated the crucial role played by the host immunity defense mechanism and it had been hypothesized that immune modulation may have favorable impact in treating recurrent URTIs. Most children suffering from URTIs, receive antimicrobials, which are seldom necessary. These antimicrobials are associated with risk of various short- and long- term adverse events and furthermore, there is always the inherent risk of emergence of microbial resistance to these antimicrobials(.Polmar SH, (1992)).

Herbal drugs are well known to have immunomodulatory properties. These immunomodulatory agents of plant origin act by stimulating both specific and non- specific immunity(Wagner H, and Proksch A,(1983)).

In recent times, emphasis has been for the search of a herbal formulation which can be helpful in the management of immunity related disorders. One of the main strategies in Siddha medicine is to increase body's natural resistance to disease/ stress causing agent rather than directly neutralizing the agent itself. This has been achieved by using extracts of various plant material called rasayanas. This concept in modern scientific understanding relates to enhancement of immune response of an organism against the pathogens by non-specifically activating the immune the immune system using immuno-modulating agents of plant origin. It is now being recognized that immunomodulatory therapy could provide an alternative to conventional chemotherapy for a variety of disease conditions (Saraf. M.N, and Bhide M.B, (1983)).

Reference: Guppusamy Siththa vaithiya theraddu

Peenisa hair oil is a poly herbal formulated from

1.Vitex negundo	750mlextracts of the leaves
2.Alternanthera sessiles	750ml extracts of the leaves
3.Alpina galangal	15g
4.Piper longum	15g
5.Ricinus communis (root)	15g
6.Wrightia tinctoria	15g
7.Cassia sophera	15g
8.Zingeber officianale (dry ginger)	15g
9.Saussurea lappa	15g
10.Strychnos potatorum	15g
11.Peucedanum graveolens	15g
12.Emblica ribes	15g
13.Glycyrrhia glabra	15g
14.Sodium chloride impure	15g

Vitex negundo has astringent , anti-inflammatory, analgesic (possibly mediated via prostaglandin synthesis inhibition), antihistaminic, membrane stabilizing and antioxidant activities(Dharmasiri MG, Jayakody JR, Galhena G, Liyanage SS, Ratnasooriya WD, (2003)). In one study, the flavonoid – rich fraction (5,7,3' –trihydroxy, 6,8,4'-trimethoxy flavones) of Vitex nigundo was found to antagonize the androgenic action of exogenous testosterone propionate(Bhargava SK, (1989).

Chemical examination of leaves and pods of Wrightia tinctoria resulted in the isolation of a- amyrin, â-sitosterol(Rao, M,N, Rao E.V. and Rao .V.S. (1966)).

oleanolic and ursolic acids(Rao, M,N, Rao E.V. and Rao .V.S. 91968)).

indigoand wrightial (Ramachandra, P, Basheermiya .M, Krupadanam G,L,D, and Srimannarayana .G, (1993).

Tryptanthrin, one of this plant is shown to possess antimicrobial (Handa .G, Tabata M, (1979)).

antifungal, Anti –inflammatory activity of the trypanthrin and a –amyrin acetate present in the leaves of this plant(. Safayhi, H, Sailer .E.R,(1997)).

Objective

This study was aimed to evaluate the clinical efficacy, short –and long-term safety of Peenisa oil in treatment and prevention of Peenisam.

Methodology

Type of Study - Clinical trial.

Population - 192 patients.

Place- Private Dispensary, Jaffna.

Study Period - Aug. 2008 - Dec. 2008

Inclusion criteria

One hundred and ninety two patients of both sexes, from the age group of 08- 40 years, who were clinically diagnosed as suffering from mild to moderate peenisam and who were willing to gave informed consent were enrolled in the study.

Exclusion criteria

Patients with severe peenisam, endocrine disorders will exclude from the study.

Study Procedures

All enrolled patients underwent a through clinical examination, with special emphasis on local examination. The patients were divided into two groups. Group- I received Peenisa hair oil and placebo of Gingelly oil.

Treatment Schedule was

Group I (n= 102) Peenisa oil 30 ml hair once daily for a period of 3 months with gentle massage to the entire scalp

Group II (n =90) Gingelly oil 30 ml hair once daily for a period of 3 months with gentle massage to the entire scalp.

The patients were asked to assess and record twice daily (morning and evening) on a card the severity of seven individual symptoms, sneezing, itch nose and eyes, blocked nose, running of the nose, malaise, prevention of smell, fullness in the ear/ diminished hearing. The patients were asked to score symptoms as follows: 0:-no symptoms; 1- symptoms present but not troublesome; 2- symptoms troublesome but not interfering with normal activities; 3- symptoms interfering with normal activities and sleep.

Duration of therapy

At the end of treatment lasting 3 months the overall symptom control for each individual patient was assessed as 1- excellent; 2- good; 3- satisfactory; 4- poor; 5 abysmal and adverse experiences were recorded. The patients were followed up for a further period of 2-3 weeks and recurrence of symptoms, if any, was recorded.

Adverse events

All adverse events reported or observed by patients will be recorded with information about severity, date of onset, duration and action taken regarding the study drug. Relation of adverse events to study medication will be predefined as "unrelated" (a reaction that does not follow a reasonable temporal sequence from the time of administration of the drug), "Possible" (follows a known response pattern to the suspected drug, but could have been produced by the patients clinical state or other modes of therapy administered to the patient), and "Probable" (follows a known respond pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient clinical state).

Patients were allowed to voluntarily withdraw from the study if that experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For patients withdrawing from the study efforts will be made to ascertain the reason for dropout. Non – compliance will be not regarded as treatment failure and reasons for non- compliance were noted.

Results

At the 192 patients enrolled in the study, 102 were allocated to Peenisa oil and 90 to Gngelly oil.

Table 1 self-assessment scores before and after treatment

	Group -1 (Peenisa oil) n = 102		Group -2 (Gingelly oil) n=90	
Parameter	Pre –treatment	Post-treatment	Pre –treatment	Post-treatment
Sneezing	2.35	0. 23	2.83	2.25
Itching nose/eye				
Blocked nose	1.68	0.01	1.96	1.81
Running of nose	1.43	0.25	0.92	0.82
Malaise				
Prevention of	1.22	0.26	1.32	1.30
smell	1.60	0.01	1.50	1.28
	0.80	0.14	1.12	1.03

The mean values for each of the seven rhinitis symptoms assessed by the patients themselves before and after treatment of period of 3 months. Peenisa oil group controlled the symptoms in most of the patients and were assessed in regarded to efficacy.

Discussion

In the present study the efficacy and safety of peenisa oil Siddha formulation ,was compared with the Gingelly oil in patients of acute rhinitis. Peenisa oil is reflected in the reduction in patients; self-assessment scores. No ad versed drug reaction were observed.

Conclusion

Peenisa oil is well tolerated with hardly any adverse reactions and is as efficacious in the treatment of allergic rhinitis.

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