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A STUDY OF SIDDHA DRUG OMA KUDINEER FOR TREATMENT OF ACUTE NASO PHARYNGITIS IN PEDIATRIC AGE GROUPS-CASE STUDY

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ABSTRACT
Acute naso pharyngitis is commonly know as common cold. It is an inflammation of the mucous membranes of the upper pharynx, the naso pharynx or the naso pharyngeal duct which extends between the oral and nasal palate. Its also refer as upper respiratory infection or rhinitis. Its is very common pathology among children and adolescents. According to siddha acute naso pharyngitis is compared to neer kana maantham based on the symptoms and the efficacy of siddha treatment is assessed. In present 40 cases of acute naso pharyngitis two time assessment was done with total blood count. One before the treatment and second after the treatment. patients aged from 2 -12 yrs in both gender were taken and treated with oma kudineer for 7 days. and clinically improvement in symptoms and blood assessment was taken. This shows that siddha treatment in pediatric age group is very useful in treating diseases like acute naso pharyngitis.

KEYWORDS: Acute naso pharyngitis, oma kudineer, siddha, pediatric, oma kudineer.

INTRODUCTION
Acute naso pharyngitis is commonly know as cold. It is an inflammation of the mucous membranes of the upper pharynx, the naso pharynx or the naso pharyngeal duct which extends between the oral and nasal palate. Its also refer as upper respiratory infection or rhinitis. A virus or bacteria can cause naso pharyngitis. Although viruses causes most acute naso pharyngitis episodes, group A streptococcus causes 37% of infection in children older than 5 years, other bacterial cause of infection are group C streptococcus (5%), anaerobic species (1%). Between viruses Rhino virus, Corna virus and Adeno virus account for the 30% of total case. It can spread through tiny air droplets that are expelled when a person infected sneezes.

Naso pharyngitis exists latently in a large number of people and pathological examination revealed the presence of inflammation in all subjects aged from 12hours after birth to 80 years. Streptococcal pharyngitis has a peak incidence in early school years. Illness occurs most often in winter & spring. The infection is transmitted via respiratory secretions and the incubation period is 2-5 days. Communicability of infection is highest during acute phase and in untreated people gradually diminishes over a period of weeks.

The symptoms of the common cold are believed to be primarily related to the immune response to the virus. The mechanism of this immune response is virus specific. For example, the rhinovirus is typically acquired by direct contact; it binds to human ICAM-1 receptors through unknown mechanisms to trigger the release of inflammatory mediators. These inflammatory mediators then produce the symptoms. It does not generally cause damage to the nasal epithelium. The respiratory syncytial virus (RSV), on the other hand, is contracted by direct contact and airborne droplets. It then replicates in the nose and throat before frequently spreading to the lower respiratory tract Respiratory syncytial virus does cause epithelium damage. Human parainfluenza virus typically results in inflammation of the nose, throat, and bronchi. In young children when it affects the trachea it may produce the symptoms of croup due to the small size of their airways.

Clinical Manifestations
In Younger Children
• In General, children 3 months-3 years have fever in the early course of infection.
• Few hours before onset of fever, sneezing, irritability and restlessness present.
• Nasal discharge begins within few hours quickly leading to nasal obstruction.
• A few infant may vomit and some have diarrhea

In Older Children
• The initial symptoms are dryness and irritation in the nose, these symptoms follow with in few hours
• Watery nasal discharge

• Sneezing
• Coughing
• Muscular aches
• Head aches
• Malaise
• Anorexia
• Low grade fever may be present

Common cold complications
• Sinus infection (acute sinusitis) Acute sinusitis is characterised by inflammation and swelling of the mucous membranes that line your sinus cavities
• Asthma attack
• Acute bronchitis (chest cold)
• Sore throat and tonsillitis.
• Acute suppurative otitis media
• Pneumonia.

MATERIALS AND METHODS
The study was conducted in government siddha medical college, Chennai, Tamil Nadu State, India where an average of 100 pediatric patients per day are visiting for Siddha system of treatment in Out-Patient-Department (OPD). There are six (6) consultation rooms and the Post-Graduate (P.G.) specialty Departments attend to the patients with assistance of faculty members and P.G. students. The OPD functions on all the 365 days of the year with the consultation hours from 8.00 AM to 12.00 Noon. All health care services are rendered free of charge. Patients irrespective of caste, creed or religion visit and avail the Siddha treatment. The Hospital is equipped with Biochemistry, Clinical Pathology, Microbiology Laboratory divisions and provides diagnostic services for treatment.

Clinical Studies
After finishing the toxicity studies 40 paediatric cases were selected on the basis of inclusion criteria from the OPD of Kuzhanthai Maruthuvam Department, Arignar Anna Govt Hospital, Chennai. They were treated with the trial drug Oma kudineer and observed for prognosis clinically.

Study Design
An open clinical trail on Neer kana Mantham was carried out in the post graduate department of kuzhanthai maruthuvam in Govt. Siddha. Medical. College attached to Aringar Anna Hospital of Indian Medicine, Chennai-106 during the period of 2015-2017.

The study was approved by Institutional Ethics Committee [IEC] and the approval number is **IEC No: GSMC-CH-ME-4/020/2015.**

Sample Size
The study is conducted in 40 selected patients of both genders between age groups of 2 to 12 years

Study of drug
Toxicological study- Acute toxicity
Pharmacological study-Anti-inflammatory
Physico-chemical analysis

Inclusion Criteria
• Age 2-12 yrs.
• Running Nose.
• Cough.
• Fever
• Malaise.
• Diarrhoea.

Patient having any three symptoms are included in my trial.

Exclusion Criteria
• Allergic Rhinitis
• Bronchitis.
• Bronchial Asthma.
• Severe Diarrhoea.

Withdrawal Criteria
• Exacerbation of the symptoms.
• Occurrence of any adverse effects.
• Patients turned to unwilling during follow up.

Assessments and Investigations
Clinical Assessment
• Rhinorrhea.
• Cough.
• Fever.
• Malaise
• Loss of appetite

Routine Tests and Investigations
Blood: TC, DC, ESR, Hb.
Urine: Albumin, Sugar, Deposits.
Methodology of Treatment

Study Enrolment
Patient reporting at the OPD associated with clinical features of Running nose, cough, fever, malaise, fatigue are chosen for enrolment based on the inclusion criteria. The patients who are enrolled are informed about the study trial drug, possible outcomes and the objectives of the study in the language ant terms understandable to them and then informed consent/assent would be obtained from the patient/patients parent using consent/Assent form.

Conduct of the Study
The trial drug will be given in the OPD department of Kuzhanthai Maruthuvam, GSMC, Chennai. The patients will be asked to have a regular follow up in the OPD department once in 3days. In each and every visit the clinical assessment will be recorded in the prescribed proforma. The laboratory investigation will be done before and after treatment and recorded in the prescribed format.

Data collection forms
Required information will be collected from each patient by using following forms.
Form I: Screening and selection proforma.
Form II: History taking proforma.
Form III: Clinical assessment proforma.
Form IV: Clinical assessment during and after trial.
Form V: Laboratory Investigation proforma.
Form VI: Informed consent/Assent form.
Form VII: Withdrawal form.
Form VIII: Patient information sheet.

Data Analysis
After enrolling the patients in the study a separate file for each patient will be maintained and all forms will be kept in the file. Whenever the patient visits OPD during the study period necessary entries will be made in the assessment forms. The data entries and adverse events if any will be monitored by the Head of the Department.

Outcome of Treatment
Primary Outcome
Primary outcome is mainly assessed by comparing the reduction in clinical symptoms and recurrence before and after treatment.

Secondary Outcome
Secondary outcome is assessed by comparing the safety parameters before and after treatment.

Adverse effect and Serious effect Management
If the trial patient develops any adverse reactions the patient will be referred to the Pharmacovigilance department of SCRI and documented. For any adverse effect the investigator will give the proper management in the OPD.

Ethical issues
1. Informed consent/Assent will be obtained from the patient/patient's parent or guardian after explaining about the clinical trial in an understandable language
2. After the consent/Assent of the patient or patient's parent(through consent/Assent)if they fit in the criteria they will be enrolled in the study.
3. Treatment will be provided free of cost.
4. Concomitant medicines will be used if there is any need.
5. The patients who are excluded (as per the exclusion criteria) will be refer to OPD
6. In conditions of treatment failure, adverse reaction patients will be given rescue medication.

Analysis of Trail Medicine
The Acute toxicity was carried out at sathyabama university, Chennai, tamilnadu, India as per OECD guidelines-423.

The pharmavological study and physico chemical, phytochemical, Heavy metal analysis, TLC and HPTLC Analysis was carried out by Noble Research solutions, Chennai, Tamil nadu.

The Bio-chemistry Analysis were carried out at GSMC, Bio chemistry lab, Chennai, Tamilnadu.

Trail Drug
Preparation and Properties of Trial Drug
Oma Kudineer
Ref: Balavagadam, page 67
Ingredients:
1. Pepper-35gm
2. Long pepper-35gm
3. Garlic-35gm
4. Omam-35 gm

Method of preparation
All the drugs were taken equal ratio purified and grinded to the powder form. Required quantity is taken from the grinded powder and mixed with pure water and this mixture is boiled until the concentrared decotation of the ingredient is obtained
Dose:1-15ml depending upon age
Duration:7 days(twice a day)

Bio Statical Analysis
Treatment for Neer Kana Mantham(Acute Naso Pharyngitis):
The most popular non parametric statistical tool, namely, McNemer Test analysis has been employed to analyze the effectiveness with the help of hypothesis.

S.NO	Clinical Features	Before Treatment	After Treatment
		n%	n%
1	Cough	40(100)	2(5)*
2	Running Nose	40(100)	3(7.5)**
3	Fever	11(27.5)	1(2.5)***
4	Malaise	4(10)	1(2.5)****
5	Diarrhoea	0(0)	0(0)

Mcnemar's test : C.I:95% * P<0.95 **P<0.92 ***P<0.27 ****P<0.075
Software :spss 17.6 version
Number of cases:40

Inference

Since the p value is significant in all signs and symptoms. So there is significant reducing of signs and symptoms among the patients for the treatment of Neer kana maantham (Acute Naso pharyngitis). Hence it is concluded that the treatment was effective and significant.

RESULTS AND OBSERVATIONS

Age Distribution

SNO	Age	No of Cases(out of 40)	Percentage
1	2-3 years	4	10%
2	4-6 Years	14	35%
3	7-10 Years	15	37.5%
4	11-12 Years	7	17.5%

Gender Distribution

Gender	No of Patients	Percentage
Male Child	21	52.5%
Female Child	19	47.5%
Total	40	100

Clinical Prognosis

Sno	Clinical Features	Before Treatment		After Treatment	
		NO of cases (out of 40)	Percentage	NO of cases (out of 40)	Percentage
1	Cough	40	100	2	5
2	Running Nose	40	100	3	7.5
3	Fever	11	27.5	1	2.5
4	Malaise	4	10	1	2.5
5	Diarrhea	0	0	0	0

Results of Neer Kana Maantham

SNO	Prognosis	No of Cases (Out of 40)	Percentage (%)
1	Good	32	80
2	Moderate	6	15
3	Poor	2	5

DISCUSSION

The disease Neer Kana Mantham was taken for the clinical study with Oma kudineer as internal medicine. For the clinical study, 40 patients were selected based on Inclusion and Exclusion criteria. The study is conducted after the drug being screened by the Screening committee and the trial is also approved by the Institutional Ethical Committee (IEC). Animal studies are carried out after obtaining proper permission from the Institutional Animal Ethical Committee (IAEC). Hence the study is safely executed on human volunteer patients and there was no adverse drug reactions noted during the study period.

40 children with Neer kana maantham diagnosed clinically treated in out patient department of Arignar Anna Hospital of Indian Medicine, Chennai-106. They were observed for clinical improvement, laboratory investigation done and treated with trial drug.

I like to summarize this study with the following highlights.

- The efficacies of the trial drug Oma kudineer were studied and observed in this study.
- Clinical diagnosis of Neer kana maantham was done on the basis of clinical features described in Bala vagadam (siddha pediatric book)
- The cost of the trial medicines are low, comparatively economic. These drugs are easily available and the dosage is also convenient.
- The potency of the trial drug were studied by phytochemical analysis, physico chemical analysis and pharmacological analysis.
- Phytochemical analysis of the trial drug reveals that the presence of Alkaloids, flavonoids, glycosides, carbohydrates, triterpnoids, tannins, phenols & proteins.
- The physico chemical analysis of the trial drug shows the PH-6, and Ash value -2.44%, So it shows the safe and effectiveness of the drug.
- The pharmacological analysis of the drug reveals that it possesses convincing Anti-inflammatory property.
- Among the 40 cases treated, 80% cases had shown Good improvement, 15% cases had shown Moderate improvement, 5% had shown Mild improvement.
- Observation made during the clinical study showed that the trial drug was clinically effective and has no adverse effect.

CONCLUSION

Neer kana Maantham is a common disease in children and mainly caused by derangement of kaba kuttram. In this clinical study Oma kudineer was taken as Internal drug respectively. The deranged kabam is settled down by the kaarppu suvai in the trial medicine there by the medicine acts as Ethirurai maruthuvam to cure the disease. Toxicological studies showed no acute toxicity. The drug has got Anti inflammatory activity. The cost of the trial medicines are low. During the clinical study no adverse events were observed.

The clinical study confirms the efficacy of the trial drugs by reducing the clinical signs and symptoms like Cough cold, running nose, Fever, and loss of appetite. Clinical study results found to be Good in 80% cases, Moderate in 15% cases, and Mild in 5% cases. The Clinical trial conducted in selected patients was satisfactory and encouraging. The trial medicine is effective for Neer kana Maantham in children. Through this study, the effectiveness of trial drug is confirmed and re-established by the author and concluded that the trail drug "OMA KUDINEER" is effective in treatment of acute naso pharyngitis (common cold).

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