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AN OPEN CLINICAL STUDY ON *NEER KANA MAANTHAM* (ACUTE NASOPHARYNGITIS) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG *MANJANAATHI KUDINEER*

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Abstract

Maantham one of the diseases affecting the child from the age group of 3 months to 12 years. It is classified into 21types in the Siddha Pediatric text *Bala vagadam*. *Neer Kana Maantham* (Acute Nasopharyngitis) is one of the types of *Maantham* which is caused due to the derangements of the three humours (*Vatha, Pitha, and Kapha*) in mother which affects the children also. It affects the upper respiratory tract causing Fever, Cough, Running nose, Irritation of throat, Lack of appetite. It gives more trouble to the children under the age group of 2-12 years. The trial drug "*Manjanaathi kudineer*" is Poly herbal medicine may be effective to manage *Neer kana Maantham.* Clinical study results found to be Good in 33 cases (82.5%), Moderate in 5 cases (12.5%) and Mild in 2 cases (5%). During clinical study no adverse events were observed. The clinical study confirms the efficacy of the trial drug reducing the signs and symptoms. As per non parametric statistical tool, McNemar‟s test: C.I:95% *P*<0.001 **P= 0.063 ***P<0.2500, spass 16 version, 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). The clinical trial conducted in selected patients was satisfactory and encouraging. The trial medicine is effective and significant for *Neer Kana Maantham* in children.

Key words: *Neer Kana Maantham, Siddha, Manjanaathi Kudineer,* Acute nasopharyngitis.

INTRODUCTION

Siddha system of medicine which has been raised from South India is the traditional medicine. Among all the system of medicines in India it has uniqueness in diagnosing the disease and treating it. Siddha system of medicine not only cures the disease but also plays a major rolein increasing the immune system. The herbal preparation of the Siddha medicine can be given right from birth to prevent the illness.

Thereby its plays a major role in pediatric age group by increasing their immune power. And moreover, it is not harmful to their body and has no side effects. It also prevents them from further infections. Children become ill easier since they aren't built with a proper immune system. And moreover, they are prone to several pathogens from the surrounding environment. Among these they are easily affected by Acute Naso-Pharyngitis (Common cold).

The symptoms of Acute Naso Pharyngitis are cold, running nose, fever, rumbling noise in stomach, diarrhea, fatigue which are compared to the symptoms of *Neer Kana Maantham* in the Siddha literature *Bala Vagadam*. This paper deals to evaluate a Siddha herbal formulation *Manjanaathi Kudineer Chooranam* mentioned in "*Bala Vagadam*" for the treatment of *Neer Kana Maantham* (Acute Naso pharyngitis) [1,2,4].

MATERIALS AND METHODS

Study Design

An open clinical trial on *Neer Kana Maantham* was carried out in the post-graduation, department of *Kuzhanthai Maruthuvam* in Govt Siddha Medical College attached to Arignar Anna Govt Hospital of Indian Medicine, Chennai-106 during the period of 2017-2019.

The study was approved by Institutional Ethics Committee (IEC) and the approval number is GSMC-CH-ME-2/016/2017

SAMPLE SIZE

The study is conducted in 40 selected patients of both genders between age groups of 2-12 years.

INCLUSION CRITERIA

- Age 2-12 years
- Running nose
- Cough
- Fever
- Malaise
- Diarrhea

Patients having any three symptoms of the above criteria will be included in my clinical trial.

EXCLUSION CRITERIA

- Allergic Rhinitis
- Bronchitis
- Bronchial Asthma
- Severe Diarrhea with other complications.

WITH DRAWAL CRITERIA:

- Exacerbation of the symptoms Occurrence of any adverse effects
- Patients turned unwilling during follow up.

ASSESSMENTS AND INVESTIGATIONS:

A. Clinical assessment
B. Siddha assessment
C. Laboratory investigations

A. Clinical Assessment

- Rhinorrhea
- Cough
- Fever
- Malaise
- Loss of appetite

B. Siddha Assessment [3]

- Naa
- Niram

- Mozhi
- Vizhi
- Sparism
- Malam
- Naadi
- Moothiram-Neer Kuri, Nei Kuri

C. 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 is 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 and terms understandable to them and then informed consent/assent would be obtained from the patient/patient's parent using Consent/Assent form.

Conduct of the Study:

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

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 and then the investigator will be giving proper management for the adverse reaction 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 bereferred to OPD.

TRIAL DRUG-MANJANAATHI KUDINEER

Ingredients:

Nuna ilai *(Morinda Tinctoria)* – 1 pidi (70gram)

Notchi thulir (*Vitex Negundo)* – 1 pidi (70gram)

Uthamani ilai (*Pergularia Daemia)* – 1 pidi (70gram)

Kazharchi ilia **(***Caesalpinia Bonduc)*– 1 pidi (70gram)

Omam (*Carum Copticum)* – 1 varagan (4gram)

Vasambu (*Acorus Calamus)* – 1 varagan (4gram)

Chukku (*Zingiber Officinale)* – 1 varagan (4gram)

Milagu (*Piper Nigrum)* – 1 varagan (4gram)

Poduthalai kaai (*Phyla Nodiflora)* – 1 varagan (4gram)

Thippili (*Piper Longum)* – 1 varagan (4gram)

Method of Preparation

The drugs are taken in the ratio mentioned above and are purified. Then they are grinded to the powder form and mixed with pure water and this mixture is boiled until the concentrated decoction of the ingredient is obtained.

Figure 1: ***Manjanaathi Kudineer Chooranam***

Dose:

1 Sangalavu (8gram)- Twice a day daily.

Preparation of kudineer:

Add 8gram of chooranam to 60ml of water. Then boil the watertill reaches to 8ml of kudineer).

Duration: 7 days

RESULTS AND OBSERVATIONS

A total number of 40 child patients with signs and symptoms of *Neer Kana Maantham* attending PG-IV, Kuzhanthai Maruthuvam Out Patient Department in Govt. Siddha Medical College attached to Arignar Anna Hospital were observed in the present study. The observation was made and tabulated with regards to the following features.

Table 1: Clinical Prognosis of *Manjanaathi Kudineer* Before and After Treatment

S.NO	CLINICAL FEATURES	BEFORE TREATMENT		AFTER TREATMENT	
		NO. OFCASES (OUT OF 40)	PERCENTAGE	NO. OF CASES (OUT OF 40)	PERCENTAGE
1	Cough	40	100%	3	7.5%
2	Running Nose	40	100%	5	12.5%
3	Fever	6	15%	1	2.5%
4	Malaise	4	10%	1	2.5%
5	Diarrhea	0	0%	0	0%

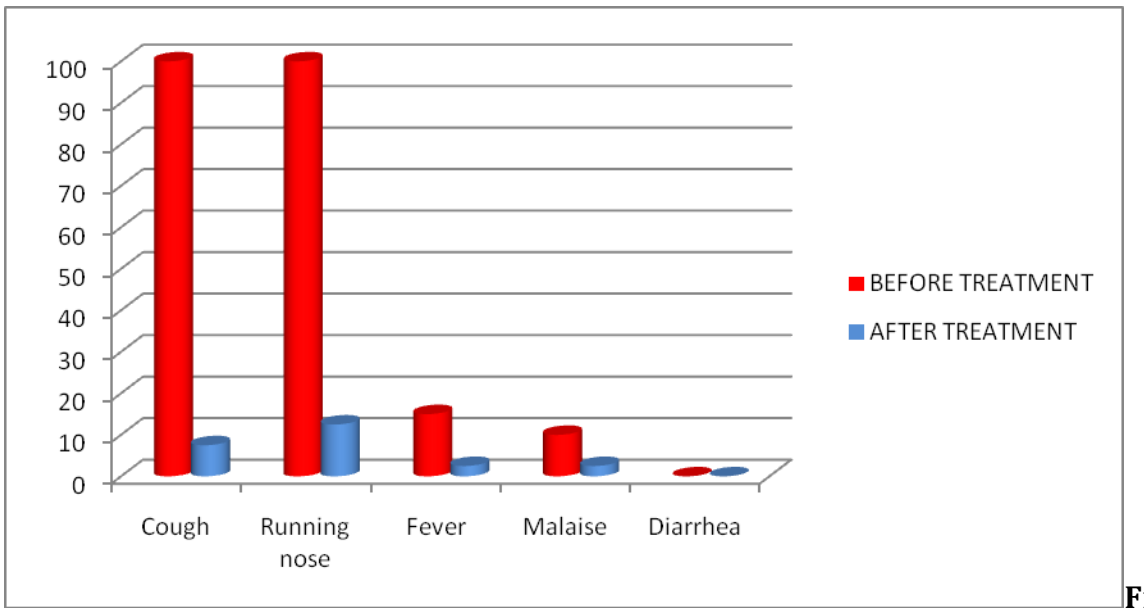

Figure 2: Clinical Prognosis of *Manjanaathi Kudineer* Before and After Treatment

Inference:

The above table reveals that, among 40 cases, 100% had cough before treatment and was reduced to 7.5%, 100% cases had running nose before treatment and was reduced to 17.5%. 15% cases had fever before treatment and was reduced to 2.5%, 10% cases had malaise before treatment and was reduced to 2.5% after treatment.

Table 3: Clinical Prognosis of *Neer Kana Maantham*

S.NO	PROGNOSIS	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Good	33	82.5%
2	Moderate	5	12.5%
3	Poor	2	5%

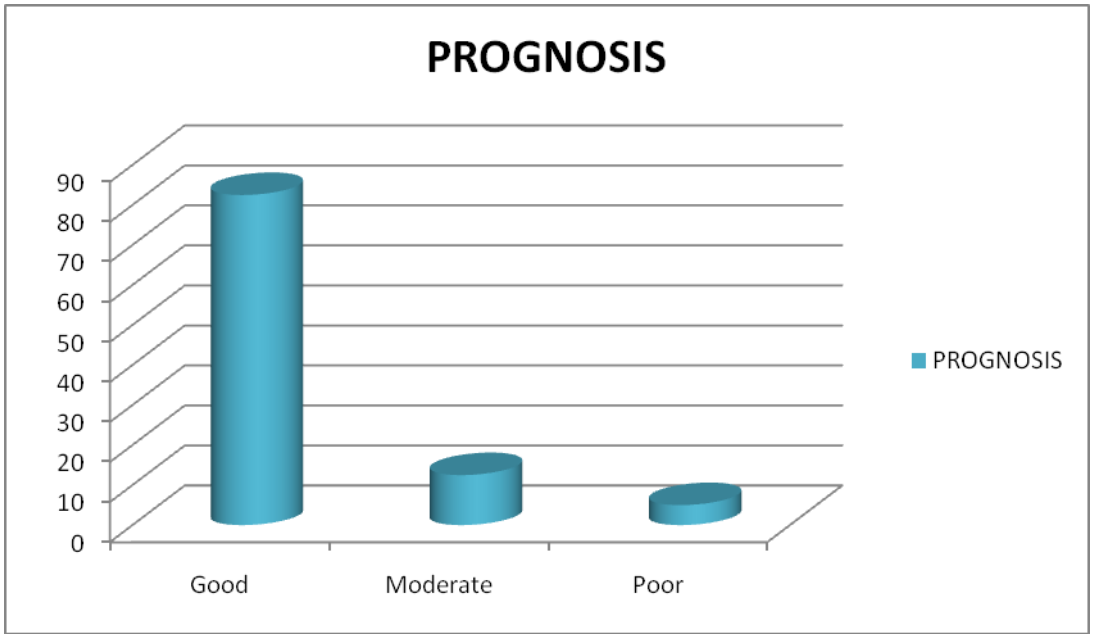

Figure 3: Clinical Prognosis of *Neer Kana Maantham*

Inference

Among 40 cases, 33 cases i.e. 82.5% showed good prognosis, 5 cases i.e. 12.5% showed moderate prognosis and 2 cases i.e. 5% showed poor prognosis.

S.NO	OP. NO	AGE/SEX	HEMATOLOGICAL ANALYSIS												Hb(gm%)		URINE ANALYSIS					
			BEFORE TREATMENT						AFTER TREATMENT								BT			AT		
			TC (Cu)	DC			ESR(mm)		TC (Cu)	DC			ESR(mm)		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
				P %	L %	E %	1/2 hr	1hr		P %	L %	E %	1/2 hr	1hr								
1	4660	21/2yrs/MC	7500	44	48	8	15	26	8600	52	45	3	10	20	12.1	12.2	Nil	Nil	Nil	Nil	Nil	Nil
2	4687	3yrs/MC	13100	43	51	6	14	20	10900	49	47	4	7	15	11.8	12	Nil	Nil	Nil	Nil	Nil	Nil
3	9036	5yrs/FC	9400	49	45	6	6	15	9600	50	47	3	4	9	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
4	9076	5yrs/FC	6800	73	24	3	21	38	7500	75	23	2	15	23	10.7	11	Nil	Nil	Nil	Nil	Nil	Nil
5	2554	6yrs/FC	7500	48	45	7	14	20	7900	49	47	4	5	10	11	11.2	Nil	Nil	Nil	Nil	Nil	Nil
6	3749	9yrs/MC	9500	61	31	8	13	22	10300	63	32	5	8	14	12.4	13	Nil	Nil	Nil	Nil	Nil	Nil
7	3802	4yrs/MC	8400	46	47	7	8	15	9200	48	48	4	5	10	14.4	14.6	Nil	Nil	Nil	Nil	Nil	Nil
8	3816	6yrs/MC	8200	52	42	6	5	12	8900	53	44	3	2	5	9.3	10	Nil	Nil	Nil	Nil	Nil	Nil
9	8563	9yrs/MC	12500	60	33	7	20	38	13100	61	34	5	15	32	11.9	12.1	Nil	Nil	Nil	Nil	Nil	Nil
10	2086	41/2yrs/MC	8900	44	48	8	14	22	9200	47	49	4	10	17	11.3	11.7	Nil	Nil	Nil	Nil	Nil	Nil
11	2035	21/2yrs/MC	8500	41	49	10	10	22	8900	42	51	7	7	16	11.5	11.8	Nil	Nil	Nil	Nil	Nil	Nil
12	2920	21/2yrs/MC	16100	69	25	6	30	59	10900	71	25	4	19	39	11.5	11.9	Nil	Nil	Nil	Nil	Nil	Nil
13	4430	5yrs/MC	12500	77	17	6	3	5	11900	79	18	3	2	4	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
14	4741	11yrs/MC	8500	47	46	7	15	24	8900	50	46	4	8	16	13.5	13.6	Nil	Nil	Nil	Nil	Nil	Nil
15	4742	8yrs/FC	9900	56	36	8	25	58	10000	58	38	4	18	45	12.6	12.7	Nil	Nil	Nil	Nil	Nil	Nil
16	4722	21/2yrs/MC	8900	47	45	8	18	38	9200	48	46	6	14	32	9	9.2	Nil	Nil	Nil	Nil	Nil	Nil
17	5327	41/2yrs/MC	15500	54	37	9	12	25	8400	52	41	7	4	10	8.8	8.9	Nil	Nil	Nil	Nil	Nil	Nil

18	5480	8yrs/MC	9000	49	42	9	7	12	9900	51	44	5	4	9	12	12.4	Nil	Nil	Nil	Nil	Nil	Nil
19	6049	4yrs/FC	9600	48	43	9	22	36	9900	51	44	5	14	22	9.2	9.4	Nil	Nil	Nil	Nil	Nil	Nil
20	6758	9yrs/FC	7500	44	48	8	15	26	8500	52	48	5	12	22	12.1	12.8	Nil	Nil	Nil	Nil	Nil	Nil
21	7248	8yrs/FC	16300	76	19	5	10	19	12300	77	20	3	6	13	13	13.6	Nil	Nil	Nil	Nil	Nil	Nil
22	7290	31/2yrs/MC	10300	72	23	5	7	15	10500	73	24	3	3	10	11.4	11.8	Nil	Nil	Nil	Nil	Nil	Nil
23	7247	31/2yrs/MC	8600	62	29	9	6	10	9300	63	33	4	3	7	11.8	12.1	Nil	Nil	Nil	Nil	Nil	Nil
24	7502	6yrs/MC	6900	40	51	9	5	15	8100	44	52	4	2	12	10.5	10.9	Nil	Nil	Nil	Nil	Nil	Nil
25	7686	4yrs/MC	7400	42	51	7	7	15	8200	53	43	4	4	12	11.4	11.8	Nil	Nil	Nil	Nil	Nil	Nil
26	4774	10yrs/FC	8600	62	3	7	5	15	8500	58	39	3	3	9	13	13.1	Nil	Nil	Nil	Nil	Nil	Nil
27	6353	5yrs/FC	10000	57	38	5	13	20	9800	58	39	3	6	13	12.4	12.6	Nil	Nil	Nil	Nil	Nil	Nil
28	7574	8yrs/MC	7200	64	30	6	5	12	8100	66	30	4	3	9	10.2	10.6	Nil	Nil	Nil	Nil	Nil	Nil
29	7706	6yrs/MC	9500	68	26	6	10	22	9800	69	27	4	6	15	11	11.4	Nil	Nil	Nil	Nil	Nil	Nil
30	8248	6yrs/FC	13100	65	30	5	10	25	12400	67	30	3	5	18	12.5	12.8	Nil	Nil	Nil	Nil	Nil	Nil
31	9070	3yrs/MC	4600	61	34	5	7	14	6300	62	35	3	4	9	11.9	12.1	Nil	Nil	Nil	Nil	Nil	Nil
32	9140	9yrs/FC	8000	40	53	7	3	5	8600	51	45	4	2	4	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
33	8999	8yrs/MC	10000	58	36	6	9	15	9800	59	37	4	4	8	13	13.2	Nil	Nil	Nil	Nil	Nil	Nil
34	393	3yrs/MC	11200	37	56	7	2	10	10800	58	38	4	2	5	11.4	11.8	Nil	Nil	Nil	Nil	Nil	Nil
35	392	7yrs/MC	15300	71	23	6	12	22	10900	69	28	3	5	16	12.1	12.4	Nil	Nil	Nil	Nil	Nil	Nil
36	1513	31/2yrs/MC	5800	58	35	7	7	15	7200	59	36	5	4	9	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
37	1640	8yrS/FC	6500	60	32	8	5	12	7300	62	34	4	3	8	12	12.4	Nil	Nil	Nil	Nil	Nil	Nil
38	2912	7yrs/FC	5700	48	45	7	25	58	6300	50	46	4	12	40	10.6	10.8	Nil	Nil	Nil	Nil	Nil	Nil
39	6264	9yrs/MC	5200	47	45	8	3	5	6800	50	46	4	2	4	12.3	12.8	Nil	Nil	Nil	Nil	Nil	Nil
40	6591	11yrs/FC	6800	52	38	10	7	15	7300	56	40	4	4	11	12.9	13	Nil	Nil	Nil	Nil	Nil	Nil

Table 4: Hematological and Urine Analysis – Before and After Treatment

BIO STATICAL ANALYSIS

Treatment for *Neer Kana Maantham* (Acute Nasopharyngitis)

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)	3(7.5)*
2	Running nose	40(100)	5(12.5)**
3	Fever	6(15)	1(2.5)***
4	Malaise	4(10)	1(2.5)***
5	Diarrhea	0	0

McNemar‟s test: C.I:95% *P*<0.001 **P= 0.063 ***P<0.2500

Software: spss 16 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 effective and significant.

SUMMARY

The disease *Neer Kana Maantham* was taken for the clinical study with *Manjanaathi Kudineer* as internal medicine. For the clinical study, 40 patients wereselected 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). Hence the study is safely executed on human volunteer patients and there were no adverse drug reactions noted during the study period. 40 children with *Neer Kana Maantham* diagnosed clinically treated in outpatient department of Arignar Anna Hospital of Indian Medicine, Chennai-106. They were observed for clinical improvement, laboratory investigationdone and treated with trial drug.

I like to summarize this study with the following highlights.

- The efficacies of the trial drug *Manjanaathi Kudineer* were studies and observedin this study.
- Clinical diagnosis of *Neer Kana Maantham* was done on the basis of clinicalfeatures described in *Bala Vagadam*.
- The cost of the trial medicines is low, comparatively economic. These drugs are easily available and the dosage is also convenient.
- Among the 40 cases treated 33 cases (82.5%) had shown Good improvement, 5 cases (12.5%) had shown Moderate improvement, 2 cases (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 the *Kaba kuttram*. In this clinical study *Manjanaathi Kudineer* was taken as Internal medicine 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

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. Through this study, the effectiveness of trial drug is confirmed and re-established by the author and concluded that the trial drug *"Manjanaathi Kudineer"* is effective in treatment of Acute Nasopharyngitis (Common cold).

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