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Clinical Study on Immunomodulatory Action of Suvarnprashan on Recurrent Upper Respiratory Tract Infection in Children – A Two-Arm Prospective Randomized Controlled Trial

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Abstract

Introduction: *Ayurveda* declares that *bala* of the body must be adequate as it ensures prevention of infections as well as promotes growth and development of a child. Childhood period is period of maximum growth and development, that have direct impact on future life of an individual. Various factors like pollution, dietary habits, lifestyle, stress affected children and prone them to various infection. This study has undertaken the immunomodulatory action of *Suvarnaparshan* on recurrent upper respiratory tract infection in children. The available data is based on clinical findings.

Aims & **objectives**: To study the immunomodulatory effect of *Suvarnaprashan* prepared from *Goghrita* in Children suffering from URTI.

Materials: Patients were OPD and IPD of *Balroga* Department of Sanjeevani Ayurved Hospital of Post graduate Institute of Ayurveda, Dr. S.R. Rajasthan Ayurved University, Jodhpur, Rajasthan & randomly divided into two groups equally i.e. 60 in each group viz- Group A – This group of 60 children was given *Suvarnaprashan*. Group B – This group of 60 children was given placebo drug. The dose of *Suvarnaprashan* was calculated according to the age of patients calculated by Young's formula. The duration of treatment was 45 days.

Result & Discussion: *Suvarnaprashan* of *Goghirta* (Group A) showed extremely significant reduction in the repeated episodes of recurrent upper respiratory tract infection. Group B drug showed less results to group a drug because it was placebo drug.

Keywords: *Suvarnaprashan, Goghrita, URTI, Immunity, Placebo*

Introduction

Childhood period is period of maximum growth and development, that have direct impact on future life of an individual. Various factors like pollution, dietary habits, lifestyle, stress affected children and prone them to various infection. Thus, there will be severely affected growth and development. Hence children are becoming the easy victim of upper respiratory tract infections. It is obvious that immune system plays a vital role in sustaining the body and prevention of various pathogenic infections. Meanwhile maintenance of the same at a higher-level lead uninterrupted physical, mental, social, and academic growth and development. At present this condition is burning problem for parents and paediatrics population, with mortality rate of 10-20% of death in developing countries [1]. WHO 2008 report the incidence of URTI especially pneumonia in children under five is estimated to be 156 million episodes each five year worldwide of which 151 million episodes are in developing countries. Upper respiratory tract infection is the most common medical cause for school and work absence, causing more than 25 million lost school days and 21 million lost workdays annum and accounting for nearly 7% of all visits to paediatrician and family physician [2].

Respiratory tract is the anatomical structure which include air moves nose, pharynx, larynx, trachea, bronchi and lungs. Respiratory tract divided in two parts. First one is upper respiratory tract and second one is lower respiratory tract. The upper respiratory tract includes the nasal and oral orifices as well as the laryngeal false vocal cords. This tract can be attacked by many bacteria, virus, and protozoal organism that led to URTI. This infection may affect the throat (pharyngitis). Nasopharynx (nasopharyngitis), sinus (sinusitis) and larynx (laryngitis). Upper Respiratory tract infections of child can be defined as, repeated episodes of cough, cold, fever, otitis media and rhinitis along with throat pain and pneumonia more than 4-5 episodes per year.

Ayurveda classics also explain the similar instances of upper respiratory tract. Infections under the heading of *Kasa*, *Shwasa*, *Pratishyava*, *Mukha Roga* with comprehensive approach to the treatment of the same. By thorough analysis of knowledge of Ayurveda, it is obvious that *Ojas* plays an effective role in prevention of such pathological consequences [3]. *Ojas* or immunity when declined due to various causes opens the door for the various infections. *Ojas* of the child is usually challenged in the childhood period due to physiological, structural, dietic, and biochemical limitations. This is not only hampering the growth of child but also responsible for reduced academic performance due to frequent school absenteeism. During periods of rapid growth and development, such events have a temporary or permanent delaying effect on it. Administration of processed gold in children is a unique practice mentioned in *Kashyap Samhita* as *Suvarnaprashana* [4] in which *Acharya Kashyap* explained evidently the administration of *Suvarna* with *Madhu* & *Ghrita* for improving intellect, digestion, physical strength, and immunity.

Need of Study

Children up to five-year age are especially vulnerable to various infections due to not fully developed immune system. Upper respiratory tract infection is one of the infections which occurs repeat in winter and autumn season. Such frequent infection affects the physical as well as mental growth and development of the children. Upper respiratory tract infections are a common problem among children, typically occurring as often as six to eight times a year [5]. In this period attempt should be done for prevention of disease and to enhance physical and mental well-being of children. Modern medical science has no proper management to prevent these children from recurrent infections and to boost body's immune system. In ancient classic various *Acharya* mentioned some immunomodulatory recipes like *Suvarnaprashan* to protect children from such type of infections and to enhance physical growth and mental development of a child. So, keeping all scenario in mind and to find out a better solution. This study was planned for this *Suvarnaprashan* was selected as immunomodulatory drug. This was mentioned in *Kashyap Samhita* under *Sutrasthana*.

Aims and Objectives

i. To study the immunomodulatory effect of *Suvarnaprashan* prepared from *Goghrita* in Children suffering from URTI.

ii. To collect data on immunomodulation property of *Suvarnaprashan* available in Ayurveda & Modern science.

Methodology

The trial was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2006), and that are consistent with Indian/ICH Good Clinical Practices (GCP) guideline Prior to commencement of trial, the protocol, the participant information sheet, and consent form was submitted to the IEC.

IEC Approval

IEC order no. DSRRAU/UCA/IEC/19-20/312 dated 08/07/2020 CTRI REGISTRATION

Prior to the start of trial, the study was applied for registration in CTRI with reference number REF/2021/04/043091 AU and in 01-jun- 2021 trial was registered to CTRI with registration No. CTRI/2021/06/034161

Study Design

i. Type of study: Interventional

ii. Interventional model: Two group assignment

iii. Allocation: Randomized with lottery method

iv. Masking: Double Blind

v. Purpose: Treatment

vi. Timing: 45 days

vii. End point: Efficacy

Diagnostic criteria

Inclusion Criteria

a. Children of age group of birth to 1 to 5 years of both sexes were selected.

b. Children having recurrent episodes of recurrent URTI were selected.

Exclusion Criteria

a. Children having age less than 01 year and more than 5 years were excluded.

b. Children having congenital anomalies, chronic pulmonary disease like pulmonary tuberculosis, chronic lung disease, in error of metabolism, chronic hematological disorders and chronic gastrointestinal disorders etc were excluded.

Discontinuation Criteria

i. During clinical trial, if child develop any serious condition which requires urgent treatment was eliminated from study.

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ii. Parents of children those was not agreeing to continue trial.

Side Effect Evaluation Criteria

To evaluate untoward effect a proforma was developed during study.

ADR

All ADR was noted in a proper format and was reported to pharmacovigilance cell of UCA Jodhpur.

Source of Patients

120 children of both sexes were randomly selected from OPD & IPD of Post Graduate Institute of Ayurved, Jodhpur and Kaniram Salagram Satellite Ayurved Hospital, Magra Punjala, Jodhpur, Rajasthan and equally divided in two groups' viz. Group A & Group B.

Grouping and Posology

Grouping and posology were mentioned in Table 1.

Follow up: The follow up and assessment of the children was done on the basis of subjective parameters during trial. Total follow up period was of 06 months.

Trial Drug

Suvarnaprashana

Ingredients - Trial Drug: -1. Suvarna Bhasma 2. Madhu 3. *Goghrita* Placebo Drug: -1 Madhu 2. *Goghrita*

Drug Preparation: - *Goghrita* was prepared from fresh cow milk. During the preparation of drugs SOP of *Ghrita* preparation was followed. Trial drug and placebo having honey and *Goghrita* was mixed and prepared and blinded in pharmacy of Post Graduate Institute of Ayurveda, Dr. S. R. Rajasthan Ayurved University, Jodhpur under the supervision of pharmacist. Suvarna Bhasma was purchased from a standard GMP certified company. Madhu was used as per AFI standard and purchased from standard GMP certified company.

Preparation of Drop

The provisional drug was prepared by mixing *Suvarna Bhasma*, *Madhu* & *Goghrita*. *Madhu* and *Goghrita* was taken in unequal quantity in a ratio of 60:40 and quantity of *Suvarna Bhasma* was added in the compound as per description available in classical textbook and with the help of Modern dose conversion formulae.

Dosing

Dose of *Suvarna* (gold) mentioned in the *Rasa Tarangini* was considered as standard adult dose. As per the *Rasa Tarangini* the dose of *Suvarna Bhasma* is 1/8 to 1/4 *Ratti* in adults [6]. 1/8 to 1/4 *Ratti* =15 mg to 30 mg. This adult dose of *Suvarna* (gold) will be utilized to calculate paediatric drug dose of Suvarna (gold). For this purpose, Fried's Formula will be used (Table 2).

Assessment Criteria

During the trial children will be assessed based on subjective parameters and objective parameters.

Subjective Parameters

The improvement was assessed mainly based on relief in the signs and symptoms of the in the children.

To assess the effect of therapy, all the signs and symptoms was given scoring depending upon their severity. The improvement in children will be assessed mainly on the basis of relief in symptoms & sign as given below in Tables 3 & 4.

Table 1: Showing Grouping & Posology.

Name of drugs	Group A (*Suvarna Bhasma* +Honey + *Goghrita*)	Group B (Honey+ *Goghrita*)
Number of Children	60	60
Type of study	Interventional	Interventional
Masking	Double Blinded	Double Blinded
Control	Controlled	Controlled
Timing	Prospective	Prospective
Duration of Drug trial	45 Days	45 Days
Dosage	According to age	According to age
Time of Administration	Once daily	Once daily
Route of Administration	Oral	Oral
Presentation	Oral drop	Oral drop

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Table 2: Depicting dose of *Suvarna* & dose of *Suvarnaprashana* according to age.

Sr.no	Children age	Approximately *Suvarna* given in drops	Dose of *Suvarnaprashana* in drops
	1-2	2.50 mg	2
	2-3	3.75 mg	3
	3-4	5 mg	4
	4-5	6.25 mg	5

Table 3: Depicting anthropometric parameters.

S.NO.	Particulars	Before trial (1st dose)	After trial (last dose)
1.	Height		
2.	Weight		
3.	MAC		
4.	Head Circumference		
5.	Chest circumference		

Table 4: Showing Grading Scores of signs and symptoms decided as per their severity.

Objective Parameters

Following instruments were utilized for physical examination.

i. Stadiometer for measuring height of children above 1 year of age.

ii. Weight in children older than 1 year was measured with electronic/ digital weighing machine.

iii. Inch tape was used for measuring mid arm circumference and chest circumference in children.

Laboratory Investigations

Assessment of the therapy were also carried out by comparing the before treatment and after treatment values of objective parameters viz-complete blood count, ESR, CRP, Chest X-Ray (PA view if needed) and Immunoassay IgG & IgM (for immunoassay 20 patients will be selected randomly from each group and ELISA test will be done of these patients Before Treatment (Baseline) and After Treatment).

Observations

Total 135 children were registered in the present clinical study. Out of them 120 children completed the treatment, and 15 children were drop out during treatment. 66 cases registered in Group A out of which 60 children completed the treatment and 6 children discontinued. In Group B total 69 children were registered, out of which 60 completed the treatment and 9 discontinued.

Age

In the present study 19% children were of 1-2 yrs. age group, 17% children were of 2- 3yrs age group, 27% children were of 3-4year age group, and 47 children were found 4–5-year age.

Gender

In the present study 57.5.5%, children were found males followed by 47.5% female children.

Religion

In the present study maximum number 99.16 of children were Hindu, followed by 01.84 of children were Muslim.

Socio economic state

The cases were classified in three groups according to their economic status i.e. lower class, lower middle class, middle Class, upper middle class, and upper class. It was observed that 17% parents were from lower class, 23% belonged to lower middle class, 39% belonged to middle class,18 % were belongs to upper middle class and 3% from upper class.

Habitat

In present study 52.5 %, children were resided in urban areas while 47.5% children were resided in rural area.

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Dietary Habits

In present study maximum 85 (71%) patients were vegetarian and 35 (29%) patients were mix vegetarian.

Deha Prakriti

The study of incidence of Deha prakriti among 120 children revealed that maximum children i.e. 15% were of *Vata Pittaja Prakriti* followed by *Vata Kaphaja Prakriti* were 48% and *Pitta Kaphaja Prakriti* were 37%.

Manasika Prakriti

The study of incidence of *Manasika Prakriti* among 120 children revealed that maximum children i.e. 46% were of *Rajasika Tamasika* prakriti followed by *Tamasika - Satavika Prakriti* (12%) and *Satvika-Rajasika Prakriti* (42%).

Samhanana

In present, study out of 120 children, maximum (61%) children had *Madhyama Samhana* followed by 39 % children had *Hina Samhanana*.

Satmya

Out of 120 patients *Satmya* was observed as *Madhyama Satmya* in maximum 59% children, followed by 34 % *Avara Satmya* and 7 % *Pravara Satmya.*

Satva

Out of 120 patients Satva was observed as *Madhyama Sattva* in maximum 57% children, followed by 33% *Avara Sattva* and 11 % *Pravara Sattva.*

Sara

The incidence of Sara wise distribution found in 120 children revealed that 63% children were having *Vyamishra Rasa Satmya* followed by 37% *Ekrasa Satmya.*

Ahara Shakti

The *Abhyavarna Aahar Shakti* wise distribution of the children showed that 54% of the children had *Madhyama Abhyaharan Shakti*, followed by *Pravara Abhyaharan Shakti*(19%), *Avara Abhyaharan Shakti*(27%). Similar trend was seen in *Jarana Aahar Shakti* with *Madhyama Jaran Shakti* in 58%, *Pravara Jaran Shakti* in 18% and Avara Jaran Shakti in 24% of the children.

Vyayama Shakti

Out of 120 patients *Vyamshakthi* were observed as *Madhyama Vyamshakthi* in maximum 53% children, followed by 27% *Avara Vyamshakthi* and, 20% *Pravara Vyamshakthi.*

Vaya

Out of 120 patients in 81% Children were *Annada Vaya* and 19% Children were 19% *Ksheerannada*.

Agni

It was observed that maximum children (39%) had *Mandagni* followed by *Vishamagni 30*%, *Samagni* (23%) and *Tikshnagni* (7%).

Desha

All the patients who were suffering from RURTI, they all were related to *Jangaldesha*.

Koshtha

The study of *Koshtha* incidence revealed that 61% children were of *Madhyam Koshtha,* followed by 29 % *Krura Koshtha* and 10% *Mridu Kostha.*

Nidra

The incidence of sleep found in 120 children showed that maximum children 58% were having 8-12 hours *Nidra* followed by4-8(24% hours *Nidra*), and 12 hours above *Nidra*(18%) and 0-4 Hours *Nidra* 0%.

Addiction

Above table shows, that out of 120 children no addiction was observed in 77% patients while tea addiction was observed in 23% patients.

Statistical Analysis

For Nonparametric Data Wilcoxon matched pairs signed ranks test was used while for Parametric Data Paired 't' Test was used and results calculated in each group. For calculating the Inter group comparison, Mann-Whitney Test & Unpaired't' Test were used.

Result

Intragroup and Intergroup results are shown in table no-5 to 11 as given below.

Intragroup Study

Discussion

In this comparative study, the efficacy of *Suvarnaprashana* has been studied in groups A and B respectively.

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Intragroup

Effect of Therapy on Subjective Parameters (Table 5)

Table 5: Showing effect of therapy on subjective parameters.

Sore Throat	
No sore throat	G0
Mild sore throat	G1
Moderate sore throat	G2
Severe sore throat	G3
Sneezing	
No attack per day	G0
1-5 sneeze attack per day	G1
6-10 sneeze attack per day	G2
>10 sneeze attack per day	G3
Nasal Congestion	
Clear airway	G0
Mild obstruction	G1
Moderate obstruction	G2
Severe obstruction	G3
Cough	
No cough	G0
Mild cough	G1
Moderate cough	G2
Severe cough	G3
Nasal Discharge	
No nasal discharge	G0
Thin watery discharge without odor	G1
Thick discharge without odor	G2
Thick discharge with odor	G3
Fever	
No fever	G0
Mild fever	G1
Moderate fever	G2
Severe fever	G3

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Effect of therapy on sore throat

In Group A the mean score before treatment was 1.883 which lowered down to 0.6833 after treatment, with SD± 0.6051 giving a relief of 63.72% here was extremely significant (p value = 0.0001). In Group B the mean score before treatment was 1.883 which lowered down to 0.0.9333 after treatment, with SD± 0.4667 giving a relief of 50.45% here was statistically significant (p value = 0.0156).

Effect of therapy of sneezing

In Group A the mean score before treatment was 1.967 which lowered down to 0.5167 after treatment, with SD± 0.5945 giving a relief of 73.71% here was extremely significant (p value = 0.0001). In Group B the mean score before treatment was 1.933 which lowered down to 1.833 after treatment, with SD± 0.3025 giving a relief of 51.73% here was statistically significant (p value = 0.0156).

Effect of therapy of cough

In Group A the mean score before treatment was 1.65 which lowered down to 0.5665 after treatment, with SD± 0.9965 giving a relief of 65.63% here was extremely significant (p value = 0.0001). In Group B the mean score before treatment was 1.75 which lowered down0.9167 after treatment, with SD± 0.5574 giving a relief of 47.61% here was extremely significant (p value = 0.0001).

Effect of therapy of nasal congestion

In Group A the mean score before treatment was 1.783 which lowered down to 0.3 after treatment, with SD± 0.4621 giving a relief of 83.17% here was extremely significant (p value = 0.0001). In Group B the mean score before treatment was 2.067 which lowered down1.933 after treatment, with SD± 0.3428 giving a relief of 6.44% here was Very significant (p value = 0.0078).

Effect of therapy of nasal discharge

In Group A the mean score before treatment was 1.783 which lowered down to 0.3 after treatment, with SD± 0.4621 giving a relief of 83.17% here was extremely significant (p value = 0.0001). In Group B the mean score before treatment was 2.067 which lowered down1.933 after treatment, with SD± 0.3428 giving a relief of 6.44% here was Very significant (p value = 0.0078).

Effect of therapy of fever

In Group A the mean score before treatment was 1.95 which lowered down to 1.717 after treatment, with SD± 0.5635 giving a relief of 11.96% here was very significant (p value = 0.0001). In Group B the mean score before treatment was 2.033 which lowered down1.85 after treatment, with SD± 1.049 giving a relief of 9.11% here was not significant (p value = 0.1745).

Effect of Therapy on Anthropometric Parameters (Table 6)

In Group A& B; weight, height, HC and CC parameters has shown insignificant (p >0.05) result.

Effect of Therapy on Objective Parameters (Table 7)

In the present clinical study, In Group A, the result on haemoglobin, RBCs, PCV%, ESR, Neutrophils, Lymphocyte, Eosinophils, IgG and IgM was significant. In Group B, the result on haemoglobin, RBCs, PCV%, ESR, neutrophils, lymphocyte, eosinophils, IgG was not significant. The P value of Hb was 0.3270, which was statistically not significant. It showed that no difference in efficacy of both treatments.

Intergroup

Inter group comparison of subjective parameters (Table 8)

The p value of sore throat, sneezing, cough, nasal congestion and nasal discharge were 0.0001 which was extremely significant, showed that there was statistical difference in efficacy of both treatments while the p value of fever was 0.0338 which was significant, showed that there was statistical difference in efficacy of both treatments.

Effect of therapy on anthropometrical measurement in group A & B (Table 9)

In group A& B; weight, height, HC, mid arm circumference and CC parameters were shown non-significant results.

Table 6: Showing effect of therapy on anthropometrical measurement in Group A &B.

Chief Complaints	Gr.	Mean		Mean diff.	Relief %	S.D. ±	S.E. ±	P value	Significance
		BT	AT						
Sore throat	A	1.883	0.6833	1.2	63.72809	0.6051	0.07811	0.0001	ES
	B	1.883	0.9333	0.95	50.45141	0.4667	0.06025	0.0156	S
Sneezing	A	1.967	0.5167	1.45	73.71632	0.5945	0.07625	0.0001	ES
	B	1.933	1.833	0.1	51.73306	0.3025	0.03926	0.0156	S
Cough	A	1.65	0.5667	1.083	65.63636	0.9965	0.1286	0.0001	ES
	B	1.75	0.9167	0.8333	47.61714	0.5574	0.7196	0.0001	ES

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Nasal Congestion	A	1.783	0.3	1.483	83.17443	0.4621	0.05966	0.0001	ES
	B	2.067	1.933	0.1333	6.44896	0.3428	0.04426	0.0078	VS
Nasal Discharge	A	1.883	0.7333	1.15	61.07276	0.5469	0.07061	0.0156	S
	B	1.917	1.85	0.06667	3.47783	0.2515	0.03247	0.0625	NQS
Fever	A	1.95	1.717	0.2333	11.9641	0.5635	0.07275	0.0009	VS
	B	2.033	1.85	0.1833	9.016232	1.049	0.1355	0.1745	NS

Components	Gr.	Mean score		SD	SE	't'	P	S
		BT	AT					
Weight	A	15.14	15.29	0.63	0.24	1	>0.05	NS
	B	12.56	12.94	0.58	0.21	1.82	>0.05	NS
Height	A	94.75	95.25	0.93	0.33	1.53	>0.05	NS
	B	84.86	85	0.38	0.14	1	>0.05	NS
Mid Arm circumference	A	13.93	14.14	0.39	0.15	1.44	>0.05	NS
	B	14.81	14.75	0.41	0.15	0.42	>0.05	NS
Head circumference	A	45.25	45.38	0.35	0.13	1	>0.05	NS
	B	37.86	37.86	0	0	0	>0.05	NS
Chest circumference	A	44.29	44.29	0	0	0	>0.05	NS
	B	50.5	51	0.76	0.27	1.87	>0.05	NS

Table 7: Showing Effect of therapy on blood investigations of Group A & B Intergroup Study.

Investigations	GR	BT	AT	% Relief	S.D. ±	S.E. ±	T	P	S
Hb(g/DL)	A	11.724	13.275	-19.2293	2.927	0.3779	4.105	0.0001	ES
	B	8.962	9.728	-13.7032	5.445	0.703	1.089	0.2804	NS
RBCs	A	4.48	4.857	-8.41964	0.6268	0.08091	4.661	0.0001	ES
	B	3.655	3.681	148.974	0.2176	0.02809	0.9374	0.3524	NS
PCV%	A	38.564	40.18	-4.19044	5.624	0.7261	2.226	0.0149	S
	B	29.065	29.919	-2.93893	2.999	0.3871	2.206	0.0313	S
MCH (pg)	A	26.338	28.509	-8.24284	4.081	0.5269	4.12	0.0001	ES
	B	26.049	26.656	-2.33214	1.904	0.2459	2.471	0.0164	S
MCV (fl)	A	64.346	69.298	-7.69589	15169	1.718	2.883	0.0051	VS
	B	76.553	90.044	-17.6231	89.883	11.604	1.163	0.2497	NS

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ESR	A	11.617	6.217	46.4836	9.201	1.188	4.546	0.0001	ES
	B	32.85	31.267	4.818874	16.759	2.164	0.7318	0.4672	NS
WBC	A	10.012	8.084	19.26688	4.549	0.5873	3.284	0.0017	VS
	B	7.551	7.749	-2.6182	3.506	0.397	0.498	0.6199	NS
Neutrophils	A	51.635	55.6	-7.6789	10.828	1.398	2.836	0.0031	VS
	B	7.551	7.773	-2.93074	3.369	0.3815	0.58	0.5636	NS
Lymphocyte	A	41.792	37.567	10.10959	8.767	1.132	3.733	0.0002	ES
	B	394.2	394.07	0.033232	62.056	8.011	0.01635	0.4935	NS
Eosinophils	A	0.8405	0.6265	25.46104	0.09446	0.01219	17.549	0.0001	ES
	B	1.569	1.135	27.67368	2.862	0.324	1.34	0.1841	NS
Monocytes	A	0.869	0.4798	44.78711	0.9348	0.1207	3.225	0.0021	VS
	B	1.949	1.249	35.9569	3.1	0.351	1.996	0.0494	S
Basophils	A	0.102	0.4397	-33.07	0.8549	0.1104	3.06	0.0033	VS
	B	0.9268	0.7021	24.24471	2.881	0.3262	0.689	0.4929	NS
CRP	A	3.789	2.582	31.88176	4.266	0.5507	2.193	0.0323	S
	B	3.645	9.779	11.88203	2.443	0.3181	1.361	0.0893	NQS
IgG	A	733.03	699.79	18.16706	299.78	39.028	3.412	0.0345	S
	B	572.1	570.37	0.302972	97.083	12.533	0.1383	0.8905	NS
IgM	A	112.69	100.44	28.61301	49.762	6.424	5.019	0.0314	S
	B	110.98	104.59	5.755992	25.949	3.35	1.907	0.0614	NQS

Table 8: Showing inter group comparison of Group A & B.

Chief complaints	GR	Mean diff.	S.D. ±	S.E. ±	P value	Significance
Sore throat	A	1.200	0.6151	0.07811	0.0001	ES
	B	0.1000	0.3025	0.03906		
Sneezing	A	1.450	0.5945	0.07675	0.0001	ES
	B	0.1000	0.3025	0.03906		
Cough	A	1.100	0.6815	0.08798	0.0001	ES
	B	0.4500	0.5632	0.07297		
Nasal Congestion	A	1.483	0.6507	0.08401	0.0001	ES
	B	0.2333	0.4646	0.05997		
Nasal Discharge	A	0.150	0.5469	0.07061	0.0001	ES
	B	0.4333	0.6731	0.08690		
Fever	A	0.3500	0.4810	0.06210	0.0338	S
	B	0.6333	0.7123	0.09196		

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Table 9: Showing effect of the therapy on anthropometrical measurement in Group A & B.

Components	Gr.	SD	SE	't'	P	S
Weight	A	0.649	0.987	2.75	0.054	NS
	B	0.293	0.345			
Height	A	0.456	0.167	0.765	0.43	NS
	B	1.897	1.98			
Mid Arm Circumference	A	5.087	4.76	0.245	1.23	NS
	B	5.765	2.75			
Head circum-ference	A	5.78	2.54	0.890	0.21	NS
	B	4.76	1.45			
Chest circum-ference	A	5.98	1.98	0.798	0.87	NS
	B	0.87	1.965			

Intergroup comparison of objective parameters (Table 10)

The inter group comparison of objective parameters of both group a and b, evaluated by the unpaired t-test and it was found that, there was no statistical difference in the efficacy of both treatments.

Table 10: Showing Inter group comparison of Objective parameters overall Effect of Therapy.

Investigations	GR	Mean diff.	S.D. ±	S.E. ±	T value	P value	Signifi-cance
Hb(g/DL)	A	-1.551	2.927	0.3779	0.9842	0.3270	NS
	B	-07658	5.445	0.7030			
RBCs	A	-0.3772	0.6268	0.08091	4.096	0.0001	ES
	B	-0.02633	0.2176	0.02809			
PCV%	A	-1.883	5.830	0.7526	1.296	0.1974	NS
	B	-0.7875	2.972	0.3837			
MCH (fl)	A	-2.171	4.081	0.5269		0.0082	VS
	B	-0.6075	1.904	0.2459			
MCV	A	-6.792	16.581	2.141	0.5677	0.5713	NS
	B	-13.491	89.883	11.604			
ESR	A	5.400	9.201	1.188	1.546	0.1247	NS
	B	1.583	16.759	2.164			
WBC	A	8.084	2.487	0.3211	20.294	0.0001	ES
	B	-0.6118	2.198	0.2837			
Neutrophils	A	-3.965	10.828	1.398	1.726	0.0869	NQS
	B	-8.826	18.934	2.444			
Lymphocyte	A	4.225	8.767	1.132	0.5060	0.6138,	NS
	B	0.1310	62.056	8.011			

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Eosinophils	A	0.2140	0.09446	0.01219	0.2554	0.7989	NS
	B	0.2097	0.09137	0.01180			
Monocytes	A	0.3892	0.9348	0.1207	0.7638	0.4465	NS
	B	0.5562	1.412	0.1823			
Basophiles	A	-0.3377	0.8549	0.1104	2.473	0.0148	S
	B	-0.06267	0.1058	0.01366			
CRP	A	0.4760	2.225	0.2873	0.07687	0.9389	NS
	B	0.5092	2.493	0.3219			
IgG	A	233.17	201.78	39.028	3.229	0.0261	S
	B	1.733	97.083	12.533			
IgM	A	32.244	49.762	6.424	3.569	0.0214	S
	B	6.388	25.949	3.350			

Overall Effect of Therapy (Table 11)

The analysis of the relief percentage of the *Lakshnas Sammuchya* (overall symptoms) shows that the percentage relief for Study Group A patients was 59.88% and the percentage relief for Study Group B patients was 06.43%. The statistical analysis of the same showed that the improvements in Groups A were extremely significant and Group B were not quite significant.

Table 11: Overall effect of therapy.

Groups	N	Mean B.T.	Mean A.T.	Mean Dif.	% Relief	S.D.	S.E.	T	P
Group A	60	1.85	1.60	1.09	59.88	0.6281	0.0810	6.72	0.0001
Group B	60	1.83	1.71	0.11	06.43	0.4286	0.0554	5.06	0.0512

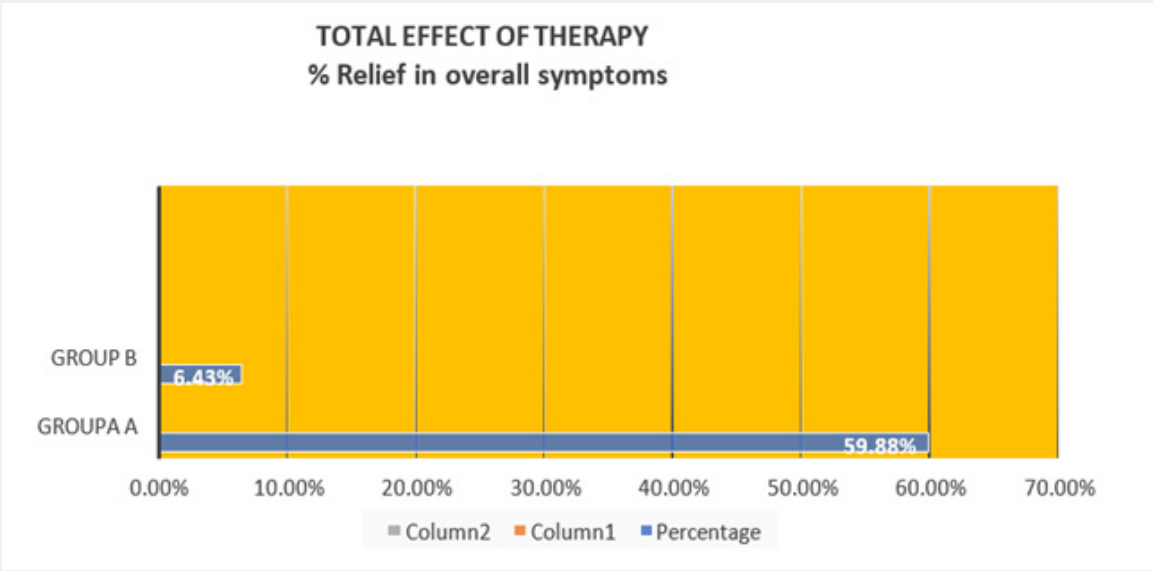

Figure 1: Lakshana Sammuchya (Overall symptoms).

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Probable mode of action of Drug

Suvarna Bhasma is sheet (cold) in *Virya*, *Madhura* (sweet) in *Vipaka*, and *Madhura* (sweet), *Tikta* (bitter), *Kashaya* (astringent) in *Rasa* [7]. It also gives Strength to the body and brain (strong) (strength). It demonstrates *Brimhana Karma* (bulk-promoting action), which is expected here; an increase in the *Rasadi Dhatu* is possible and occurs gradually with the help of *Madhura Rasa* and *Madhura Vipaka*; thus, an increase in *Rasa* leads to an increase in *Rakta*, which may lead to an increase in male and female child weight [8].

Probable mode of action of Madhu

Honey is a sweet meal manufactured by insects from nectar collected from flowers by honeybees. It has *Madhura*, *Kashaya Rasa*, *Ruksha*, *Sheeta*, *Laghu* in *Guna* [9], Picchila, Sukshamarganusari, *Yogavahi* properties along with *Sheet Virya*, *Madhura Vipaka*, and *Tridoshashamak*, *Deepana*, *Varnya*, *Swarya*, *Lekhana*, *Sandhana*, *Shodhana*, *Ropana*, *Chedana*, *Sangrahi*, *Chakshushya*, *Prasadana* [10].

Probable mode of action of Goghrita

Ghrita is a mammalia creature from the animal kingdom. According to *Ayurveda*, *Goghrita* is the safest and most suited *Ghrita* for both food and medicinal reasons. *Ghrita* is a Mammalia creature from the animal kingdom. *Ghrita* is always applied to *Goghrita*. *Goghrita* an oily liquid or semi solid material at room temperature which derived from cow's milk. *Goghrita* is Sheet (cold) in *Virya*, *Madhura* (sweet) in *Vipaka*, *Snigdha*, *Guru* in *Guna* and *Madhura* (sweet) in *Rasa* [11]. According to much research *Goghrita* has active immunological [12,13], wound healing, antiulcer [14], antiepileptic [15], antistress [16], nootropic [17] and hepatoprotective [18] properties.

Conclusion

It was concluded from the present study that *Suvarnaprashana* of *Goghrita* (Group A) showed extremely significant reduction in the repeated episodes of recurrent upper respiratory tract infection. Group B drug shows less results to group a drug because it is placebo drug.

References

1. Lakshmi NB (2010) Prevalence and Factors Associated with Acute Respiratory Infections in Children Under Five in Urban Slums of Bangalore City, Karnataka. Achutha Menon Centre for Health Science Studies, Thiruvananthapuram, India.
2. Behrman, Kliegman & Jenson's Nelson Textbook of Pediatrics, 16 Edition Reprinted 2001. Infections of the Upper Respiratory Tract. Neil E. Herendeen& Peter G. Szilagy Chapter 381. ppno. 1261.
3. Trikamji Y (2014) Charaka Samhita of Agnivesh. elaborated by Caraka & Dridhabala, Ayurvedadipika commentary, Reprint edition 2014, Sutra Sthana Chapter 17, Verse 73, published By Chaukhambha Surbharati Prakashan Varanasi, India, pp. 103.
4. Tiwari PV (1996) Kashyapa Samhita, 1st Edn, Sutrasthana, 18th Chapter, Chaukhambha Vishva Bharti, Varanasi, India, p.26-28.
5. Paul G Firth, Kenan E Haver (2009) Essentials of Pulmonology, A Practice of Anesthesia for Infants and Children (Fourth Edn).
6. Shastri K (2009) Rasa Tarangani 11th edn, 15th Taranga, Motilal Banarasi Das, New Delhi, pp. 361-367.
7. Sharma SS (1994) Ras Tarangani, 11th edn, 1994 Suvarna Vigyaniya, Panchdahtarang, Motilal Banarasidas Prakashan, New Delhi, India, pp. 374-377.
8. Christian Villiers, Heidi Freitas, Rachel Coders, Marie, Bernadette Villiers and Patrice Marche (2010) Analysis of the toxicity of gold nano particles on the immune system: effect on dendritic cell functions. J Nanopart Res 12(1): 55– 60.
9. Trikamji Y (2009) Sushruta, Sushruta Samhita, Commentary of Dalhana, Nibandha Samgraha, Reprint 2009, Sutrasthana, Chapter 45, Verse No.132 Chaukhambha Sanskrit Sansthan, Varanasi, India, pp.207.
10. Sharma PV Vagbhata, Astanga Hridaya (2005) Commentary of Arundatta and Hemadri, Sarvangasundari and Ayurved Rasayan, Reprint Sutrasthana, Chapter 5, Verse 54, Chaukhambha Orientalia, Varanasi, p. 77.
11. Sharma PV Vagbhata, Astanga Hridaya (2005) Commentary of Arundatta and Hemadri, Sarvangasundari and Ayurved Rasayan, Reprint Sutrasthana, Chapter 5, Verse 37-39, Chaukhambha Orientalia, Varanasi, India, p. 73.
12. Gaikwad A (2009-2011) A pharmaco-clinical study of effect of Madhu-Ghrita and Swarna-Vacha- Madhu-Ghrita on neonates, Jamnagar. India: Institute for Post Graduate Teaching and Research in Ayurveda, P.G. Dissertation work, Gujarat Ayurved University, India.
13. Meena RK, Singhal HK, Vyas PP (2021) Suvarnaprashan: An Ayurvedic Immune Booster. Nat Ayurvedic Med 5(3): 000325.
14. Biyani DM, Verma PRP, Dorle AK, Boxey V (2011) A Case Report on Wound Healing Activity of Cow Ghee. International Journal of Ayurvedic Medicine 2(3): 115- 118.
15. Gosavi D, Premendran S John (2012) Effect of Panchgavya Ghrita on Some Neurological Parameters in Albino Rats. Asian Journal of Pharmceutical and Clinical Research 5(1): 154-156.
16. Kumar A, Kumar R, Kumar K, Gupta V, Srivas T, et al. (2013) Antistress activity of different compositions of Panchgavya and Aloe barbadensis Mill by using tail suspension method. International Journal of Innovations in Biological and Chemical sciences 7: 17-19.
17. Pandey A, Pawar MS (2015) Assessment of Nootropic Activity of Panchgavya Ghrita in Animal Models. International Journal of Scientific and Research Publications Aug 5(8): 1-5.
18. Achliya GS, Kotagale NR Wadodkar SG, Dorle AK (2003) Hepatoprotective Activity of Panchgavya Ghrita against Carbontetrachloride Induced Hepatotoxicity in Rats. Indian Journal of Pharmacology 35: 308-311.

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