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AN OPEN-LABELLED CLINICAL TRIAL ON SWARNA PRASHAN AT SPARSH HOSPITAL, PATTANKODOLI

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ABSTRACT

In *Ayurveda* administration of the gold particles in children's is considered to be a unique practice termed as Swarna *Prashana* (SP). The main ingredients include *Swarna Bhasma, Goghrita*, Honey and other herbal drugs which are useful in enhancing intellectual property. For the past several decades, clinical practices proved that SP has better Immunomodulatory effect by activating both cellular and humeral immunity. Aim: The Present trial was conducted to evaluate and document the effect of *Swarna Prashana* on children with respect to improvement in general health status and immunity at Swarna Hospital, Pattankodoli. Methodology: The trial was Open label, Prospective and Observational study in 23 children between the age group of 4 months to 60 months, regular follow-ups were taken on 0^{th}, 180th day and 360^{th} day and assessed on the basis of specially prepared Immune status questionnaires and illness dairy. Result: As parameters were ordinal in nature, "Wilcoxon Signed Rank test" is used for intra-group comparison and results were analysed and on 0^{th}, 180^{th} day and 360^{th} day it has shown significant reduction in Illness Dairy. In same way it has also shown significant results in immune status of the child. Conclusion: Swarna Prashana has a unique immune enhancing property along with improvement in general health status and intellectual health.

Keywords: *Swarna Prashana, Immune status questionnaires, Illness dairy, Immunomodulation*

INTRODUCTION

The *Ayurvedic* system of medicine has stood the test of time for four millennia or more. The use of different origin drugs like herbal, herbo-mineral, animal etc is the unique feature of Ayurvedic system. Processed metals like mercury, gold, silver, zinc and copper are commonly used in different disease conditions and the most commonly used metal is *Swarna* (gold). In Ayurveda administration of the gold particles in children's is considered to be a unique practice termed as Swarna Prashana. Acharya Kashyapa described Swarna Prashana as one among the Jatakarma Samskara[1], Acharya Sushruta has also described the procedure of administration of Swarna, Madhu and Ghrita which is given as a single dose at birth as a part of neonatal care. The specific benefits ascribed to Swarna prashana are as follows:

• Medha Agni Bala Vardhanam (improvement of intellect, digestion, metabolism, immunity, and physical strength)
• Ayushyam (promoting lifespan)
• Mangalam (auspicious)
• Punyam (righteous)
• Vrushyam (aphrodisiac)
• Varnyam (enhancement of color and complexion)
• Grahapaham (protection from evil spirits and Microorganisms)[2].

The specific benefits of Swarnaprashana according to the duration of administration have been mentioned such as:

• If administered for 1 month, the baby will become Parama-Medhavi (highly intelligent) and Vyadhibhir Na Cha Drusy ate (will not be affected by any disease)
• If administered for 6 months, the baby will become Shrutadhara (will be able to remember the things, which are just heard).

All the above-said benefits indicate the enhancement of all favourable factors required for the proper growth and development of a child, which is considered to be rapid during Shishuavavastha (infancy).

Modern Review on Gold: [3]

Gold is a group 11 element and a transition metal in the periodic table. The atomic number of this metal is 79, and its atomic mass is 196.96655. The melting and boiling temperatures of gold are respectively 1104.43^{0}C and 2807.0^{0}C. In previous studies Gold is already proved for its Immunomodulatory effects because of its antibacterial action against different organisms. Several studies on gold nanoparticles reported that it conjugates with antigen to influence activation of t-cells. As evidence-based practice is globalizing throughout the world, the majority of the population is raising a question on therapeutic efficacy associated with use of metals in Ayurvedic products which is recognized as a potential problem now a days. Hence, this trial was conducted to rule out the therapeutic efficacy of Swarna Prashana in children's by assessing Immune status and general health status of the child.

OBJECTIVES:

- To evaluate and document the effect of *Swarna Prashan* in children with respect to improvement in general health status and immunity.

MATERIAL AND METHODS

- Parents willing to administer *Swarna Prashan* to their children were screened in *Swarna Prashan* camp of Sparsh Hospital, Pattankodoli.

Selection of patients:

Inclusion criteria

1. Apparently healthy male and female children with age in range of 4 months to 60 months.
2. Parent willing to administer Swarna Prashan to their child and for regular follow up for at least one year.

Exclusion criteria

1. Male and female Children below 4 months and above 60 months.
2. Already undergoing Swarna Prashan.
3. A child suffering from any illness which in the opinion of the investigator will place the child at extra risk.

Study type: Open-label, Prospective and Observational

Centre: Sparsh Hospital, Patta Kodoli.

Method of Sampling

Children who fulfilled eligibility criteria and whose parents were willing to participate in the study and were ready to sign an inform consent form were selected for the study.

Route of administration: Oral

Parents were advised not to feed the children for half an hour after the administration.

Dosing Schedule: *Swarna Prashan* was administered at the above dose every month on the day of *Pushy nakshatra*, for consecutive 12 months. Months were considered as lunar months as per Hindu calendar.

Duration: 12-month Method of collection data

Data was collected on the following variables.

ASSESSMENT CRITERIA

Subjective criteria - Immune assessment criteria

Table No. 1 Illness Dairy

	List of frequent illness in past	Frequency of illness	Severity in grade
Day0			
Day 180			
Day360			

* Grading ref. for severity of illness

Grade 1 – Disease subsided without medication.

Grade 2 – Disease subsided immediately on commencement of medication.

Grade 3 – Disease took the entire course of medication to subside.

Grade 4 – Disease did not respond to routine medication.

Table No. 2 Immune status questionnaire (ISQ)

1. Please indicate how often your child had the following complaints in the past 12months?

Similarly, child was assessed on day 180/182 and day 365 / 366.

	Never	Sometimes	Regularly	often	Almost always
Sudden high fever					
Diarrhea					
Headache					
Skin					
Muscle or joint pain					
Cold					
Cough					

Each item of the ISQ is scored as follows:

Never=o points
Sometimes=1 point
Regularly=2 points
Often=3 points
Almost always=4 points
Table No. 3 ISQ Scoring

RAW score	Final score
>15	0
14	1
13	3
11,12	4
10	5
8,9	6
7	7
6	8
5	9
3,4	10
<2	

0 – Very poor
10 – Excellent perceived immune status
<6 – Reduced immune functioning.
Table No. 4 Immune status interpretation

Day 0/1	
Day 180 / 181	
Day 365/366	

C) How easily does the child fall sick?
Grade 0 - No symptoms after exposure to the Infectious agent
Grade 1 - Mild symptoms after exposure to the Infectious agent No need of any medication, Subsides by itself.
Grade 2 - Moderate symptoms after exposure to the Infectious agent Need medication at OPD level.
Grade 3 - Severe symptoms after exposure to the Infectious agent Need admission and course of treatment in hospital.
Table no :5 Result

Day 0/1	
Day 180 / 181	
Day 365/366	

OBSERVATION AND RESULTS:

1. <u>Age wise Distribution</u>

Among 23 infants, 3 patients (13%) have an age below 1 year, 3 patients (13%) have age 1 year, 2 patients (9%) have age 2 year, 5 patients (22%) have age 3 year, 7 patients (30%) have age 4 year, 3 patients (13%) have age 5 year.

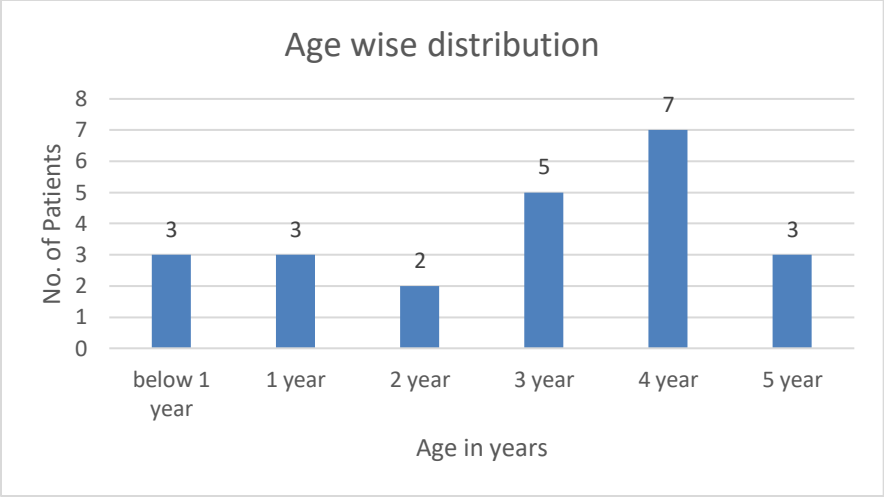


Figure No. 1 Graphical representation of age wise distribution of children's

2. Gender Wise Distribution

18 patients (78%) were Male, and 5 patients (22%) were Female.

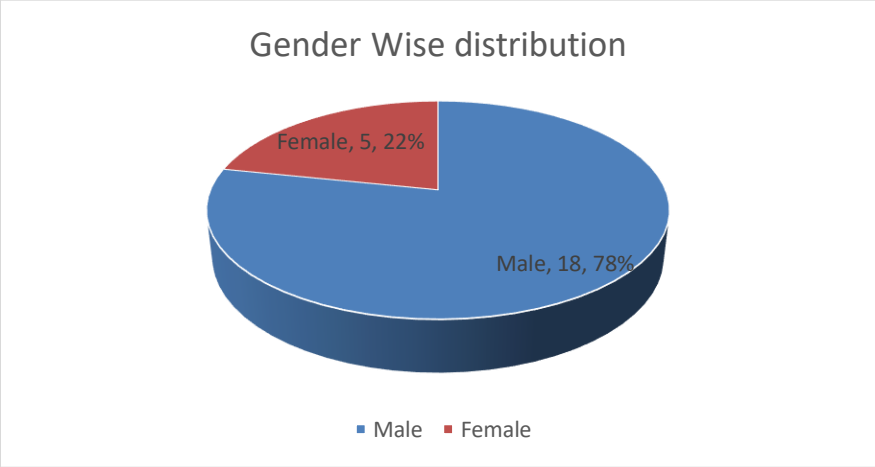


Figure No. 2 Graphical representation of Gender wise distribution of children's

Statistical analysis of different parameters:-

As the assessment parameters were ordinal in nature, "Wilcoxon Signed Rank test" is used for intra-group comparison. (i.e., before and after treatment of a group)

We have tested hypothesis for each parameter and result is interpreted accordingly. The level of significance is kept at 0.05. Proper summary statistics like contingency tables and percentages are provided along with graphics and diagrams.

1. Illness Dairy

1.1 Result At Day 180

Before treatment Day 1

After treatment Day 180

Mean score			Median diff.	IQR of diff. $Q_3 - Q_1$	Sample size	Wilcoxon signed rank test (T+)	P Value
B.T	A.T	Diff					
2.17	1.86	0.31	0.00	1.0 (1.0 – 0.0)	23	28.00	< 0.05

Using one-tailed Wilcoxon signed rank test to test the hypothesis –
H_0 : Median reduction of the illness dairy score after treatment is zero.
H_1 : Median reduction in Illness Dairy score after treatment is more significant than zero.
At day 180, the median reduction in Illness Dairy score after treatment is significant (P-value < 0.05) at a 5% significance level. **i.e., it can be said that there is a significant reduction in Illness Dairy.**

1.2 Result At Day 360

Before treatment, considered as Day 1
After treatment, considered as Day 360

Mean score			Median diff.	IQR of diff. $Q_3 - Q_1$	Sample size	Wilcoxon signed rank test (T+)	P Value
B.T	A.T	Diff					
2.17	1.0	1.17	1.00	0.0 (1.0 – 1.0)	23	276.00	< 0.05

Using one tailed Wilcoxon signed rank test, to test the hypothesis –
H_0 : Median reduction Illness Dairy score after treatment is zero.
H_1 : Median reduction in Illness Dairy score after treatment is greater than zero.
At day 360, the median reduction in Illness Dairy score after treatment is significant (P-value < 0.05) at 5% level of significance. **i.e., it can be said that there is significant reduction in Illness Dairy.**

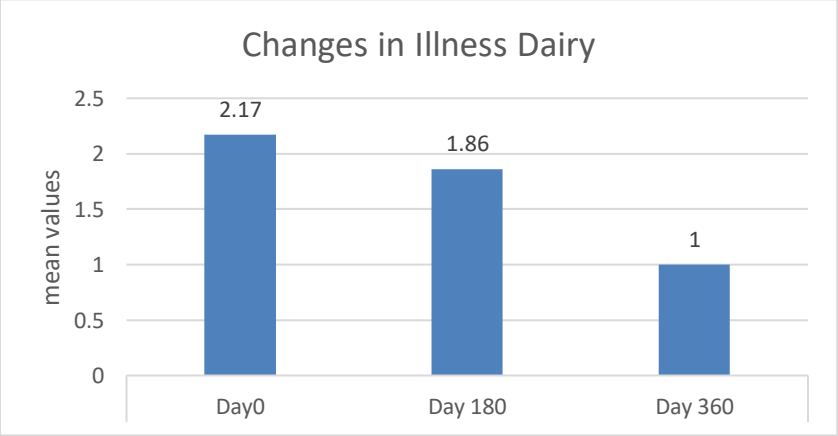


Figure No. 3 Graphical representation of changes in illness dairy

2. Immune status questionnaire

2.1 Result at Day 180

Before treatment Day 1
After treatment Day 180

Mean score			Median diff.	IQR of diff. $Q_3 - Q_1$	Sample size	Wilcoxon signed rank test (T+)	P Value
B.T	A.T	Diff					
6.52	8.73	2.21	2.00	2.0 (1.0 – 3.0)	23	0.00	< 0.05

Using one tailed Wilcoxon signed rank test, to test the hypothesis –
H_0 : Median Increase in Immune status questionnaire score after treatment is zero.
H_1 : Median Increase in Immune status questionnaire score after treatment is greater than zero.

At day 180, the median increase in Immune status questionnaire score after treatment is significant (P-value < 0.05) at a 5% significance level. **i.e., it can be said that there is a significant increase in the Immune status questionnaire.**

2.2 Result at Day 360

Before treatment, considered as Day 1
After treatment, considered as Day 360

Mean score			Median diff.	IQR of diff. $Q_3 - Q_1$	Sample size	Wilcoxon signed rank test (T+)	P Value
B.T	A.T	Diff					
6.52	9.86	3.34	3.00	2.0 (2.5 – 4.5)	23	1.5	< 0.05

Using one tailed Wilcoxon signed rank test, to test the hypothesis –
H_0 : Median increase Immune status questionnaire score after treatment is zero.
H_1 : Median increase in Immune status questionnaire score after treatment is greater than zero.
At day 360, the median increase in Immune status questionnaire score after treatment is significant (P-value < 0.05) at 5% level of significance. **i.e., it can be said that there is a significant increase in the Immune status questionnaire.**

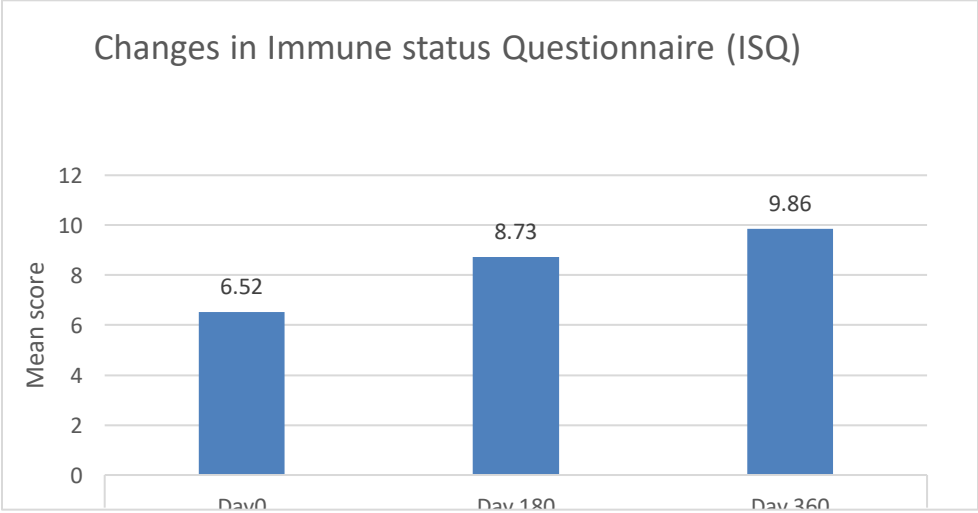


Figure No. 4 Graphical representation of changes in Immune status questionnaire

3. How Easily does the child fall sick?

3.1 Result at Day 180

Before treatment Day 1 After treatment Day 180

Mean score			Median diff.	IQR of diff. $Q_3 - Q_1$	Sample size	Wilcoxon signed rank test (T+)	P Value
B.T	A.T	Diff					
1.65	1.52	0.13	1.00	0.0 (0.0 – 0.0)	23	12.00	0.1165 > 0.05

Using one tailed Wilcoxon signed rank test, to test the hypothesis –
H_0 : Median reduction how easily does the child fall sick score after treatment is zero.
H_1 : Median reduction in how easily the child falls sick score after treatment is greater than zero.

At day 180, the median reduction in how easily the child falls sick score after treatment is not significant (P-value > 0.05) at 5% level of significance. **i.e., it can be said that there is no significant reduction in how easily the child falls sick.**

3.2 Result at Day 360

Before treatment considered as Day 1

After treatment considered as Day 360

Mean score			Median diff.	IQR of diff. $Q_3 - Q_1$	Sample size	Wilcoxon signed rank test (T+)	P Value
B.T	A.T	Diff					
1.65	0.65	1.00	0.00	0.0 (1.0 – 1.0)	23	253.00	< 0.05

Using one tailed Wilcoxon signed rank test, to test the hypothesis – H_0 : Median reduction how easily does the child fall sick score after treatment is zero.

H_1 : Median reduction in how easily the child falls sick score after treatment is greater than zero. At day 360, the median reduction in how easily the child falls sick score after treatment is significant (P-value < 0.05) at 5% level of significance. **i.e., it can be said that there is significant reduction in how easily the child falls sick.**

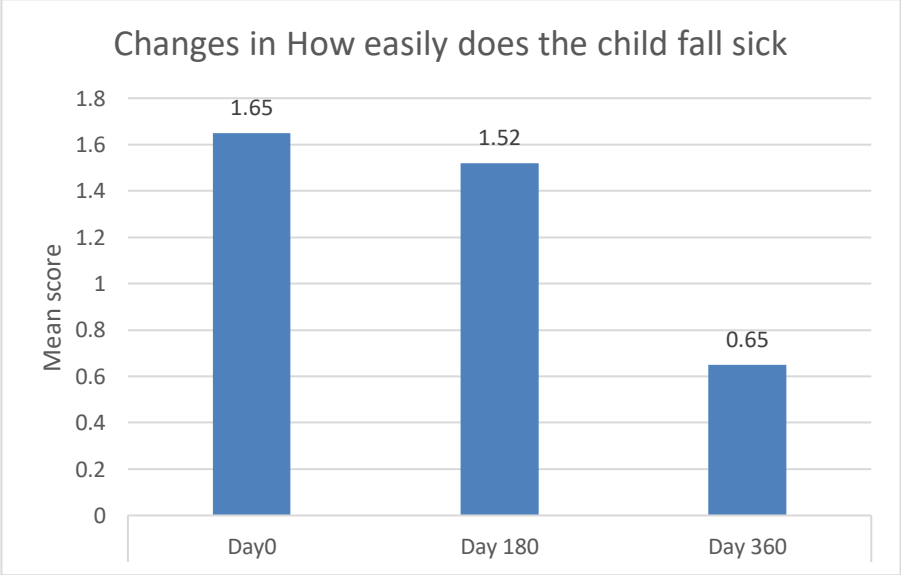


Figure No. 5 Graphical representation of changes in how easily the child falls sick.

Mean percent improvement in various Assessment parameters:

Parameters	Day 180		Day 360	
	Mean % Improvement	Remark	Mean % Improvement	Remark
Illness Dairy	12.31%	Significant	52.89%	Significant
Immune status questionnaire	40.20%	Significant	59.35%	Significant
How easily does the child fall sick	1.44%	Insignificant	70.28%	Significant
Average Mean % improvement	17.98%		60.84%	

Distribution of patients according to relief:

For assessment, all the assessment parameters were used.

Overall Effect (patient wise)	Criteria
Marked improvement	>75 % relief in signs and symptoms
Moderate improvement	>50 % to 75 % relief in sings & symptoms
Mild improvement	>25% & 50% relief in sings & symptoms
Unchanged	Up to 25% relief in sings & symptoms

Distribution of patients according to relief:

Overall Effect (patient wise)	**No. of patients**			
	At DAY 180		**At Day 360**	
	Count	**%**	**Count**	**%**
Unchanged	14	61%	1	4%
Mild improvement	8	35%	5	22%
Moderate improvement	1	4%	14	61%
Marked improvement	0	0%	3	13%
Total	**30**	**100%**	**30**	**100%**

On Day 180, 14 patients (61%) realized unchanged improvement, 8 patients (35%) realized mild Improvement, 1 patient (4%) realized moderate improvement.
On Day 360, 1patients (4%) realized unchanged improvement, 5 patients (22%) realized mild Improvement, 14 patients (61%) realized moderate improvement, 3 patients (13%) realized Marked Improvement.

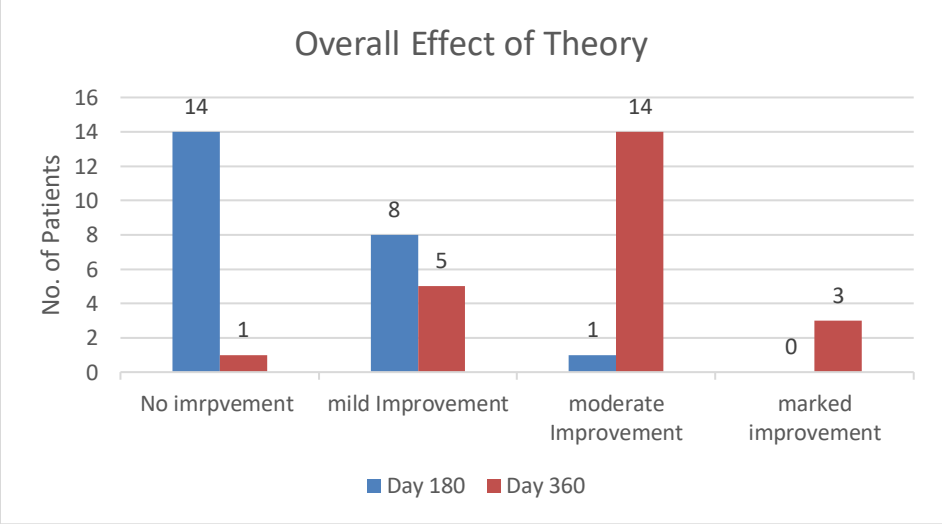


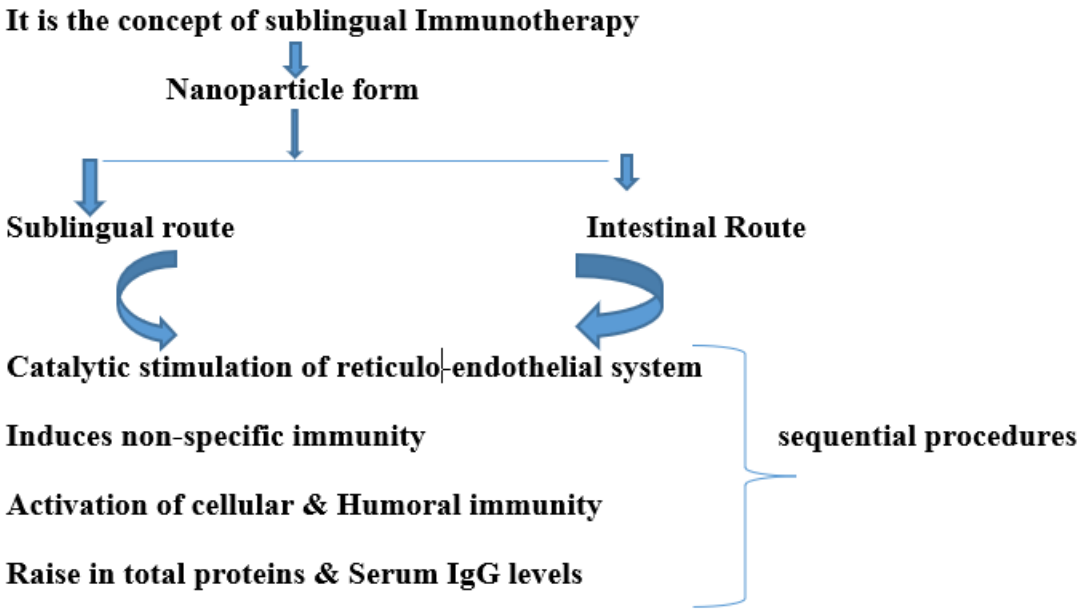
Figure No. 6 Graphical representation of overall effect of therapy

DISCUSSION

In the present study, 23 infants were registered based on the inclusion criteria. Among 23 infant's majority of infants were between the age group of 3-4 years and majority were male infants. Comparatively a smaller number of infants in the age group of less than 2 years as concern of the parent to introduce new drug composed of metal in infant. Illness dairy is a specially prepared chart which includes frequency and severity of illness episodes in children's. On the 180th and 360th day the median reduction in illness

dairy score was significant. To assess the immunity status of the child a questionnaire is used which shows significant statistical result on 180th and 360th day. As there is increased immunity the episodes of child easily fall sick also reduced.

Mode of action of Swarna Prashana:



ROLE OF CONTENTS OF SWARNA PRASHANAAS IMMUNOMODULATORY EFFECTS[4]

Swarna has the properties like that of Medhavardhanam, Agnivardhanam, Balavardhanam, Ayushyakara, Grahapaham etc. When Madhuis administered in low doses to newborns, the child gradually develops resistance to allergens, and it remains unaffected by allergic disorders. Ghrita increases mental ability, and it enhances the function of the drug added to it. It helps in the growth and development of a child. It also provides nutrition to newborns until lactation starts properly. The Swarna Prashana Samskara is an example of Virudha Satmya. Any incompatible (Virudha) substance which may be antigenic, on continuous exposure child becomes Virudha Satmya suggests that sero- negative state is converted into sero- positive state and formation of antibody is complete. Regular contact of such elements makes the body desensitized and in future there will be less effect due to formation of antibodies. Adaptiveness and modification subsequently develop as it acts as antigenic substances to the body and child will be priorly sensitized have healthy future. The same theory is used in vaccination. In Swarna Prashana Samskara, Madhu and Ghrita in equal dose along with gold is given at regular intervals, this develops resistance in the body for any type of Visha. In other words, this mixture produces non-specific immunity.

CONCLUSION

The study revealed significant statistical improvement in a child's immune system and general health. The efficacy of Swarna Prashana as an immunomodulator is evident from the study. As sample size and assessment parameters where, fewer further exploration is needed to evidently practice a safe Swarna Prashana therapy.

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