



Research Article

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Clinical survey on Hiranyaprash™ in children

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ABSTRACT

Background: Muniyal Institute of Ayurveda Medical Sciences has emerged with Dr. Krishna Life Sciences Ltd, Manipal pharmacy of high standards. It has given a wide range of classical and patent medicinal preparations which are being practiced successfully by Ayurveda physicians. One of such potent drug is 'Hiranyaprash™'-a patent medicine. The survey study and random clinical study was carried out to see the effect on various parameters by the institution. **Material and Methods:** Survey was carried out in various centers related the institution and hospital. 104 children randomly assessed for clinical study. 2 drops of Hiranyaprash™ administered to the children below the age group of 5 years and 4 drops administered above the age group of 5 years. The survey and clinical assessment was done and data obtained was analyzed statistically. **Conclusion:** Hiranyaprash™ is beneficial in preventing the respiratory manifestations and beneficial in increasing the appetite of children. Analysis of data on behavioral assessments shows high statistical significance in parameter school work performance and subject understanding ability.

Keywords: Hiranyaprash™, Survey, Patent, Assessment.

INTRODUCTION

In the present day protecting child from endless germs and viruses is the need of hour. Some pediatricians consider in a year six to seven bouts of flu or ear infections in children are normal. But there are healthy habits by which the child's immunity can be boosted and reduction in episodes of illness can be achieved. Adequate sleep, nutrition, regular exercise, hygiene maintenance, being away from allergens and germs are the good practices which can reduce the morbidity and boost the immune system.

One such practice is *SwarnaPrashana* explained in ancient literatures of *Ayurveda* which enhances the healthy status of child. Various formulations, duration of administration and benefits of *Swarnayogas* have been explained in classical texts of *Ayurveda*. *Sushruta*^[1] and *Vagbhata*^[2] have prescribed gold with various drugs to the newborn child immediately after the birth. *Sushruta* has advised to use *SwarnaPrashana* after *Vamana* of *garbhodaka* whereas *Vagbhata* advised it before *Vamana*. Both *Sushruta* and *Vagbhata* have mentioned about four gold preparations for prolonged use^{[3], [4]}. According to *Sushruta*, one year of daily administration of gold preparation is helpful in enhancing the *medha*, *ayushya*, *arogya* and *pushti*^[5]. *Kasyapa* has explained about the method of *SwarnaPrashana*, administration mode, *anupana*, duration of administration and benefits^[6]. *SwarnaPrashana* boosts immune system and prevents the various infections. It enhances the intellectual powers and memory. *Charaka* has advised use of gold immediately after birth to the newborn in the form of *jatakarma* along with honey and ghee^[7].

SwarnaPrashana is being practiced by various institutions and Ayurveda Pediatricians successfully. *Hiranyaprash™*- the patent medicine of Dr. Krishna Life Sciences Ltd, Manipal, a GMP certified unit, is found effective in clinical practice in enhancing immune system by preventing respiratory illnesses, gastro intestinal disorders and developmental problems. So the Institution took initiative to do survey and clinical study and the data was documented. Analysis was done to assess the efficacy on various parameters.

MATERIALS & METHODS

Drug

Hiranyaprash™ is a specialized research product designed and developed by Dr. Krishna Life Sciences Ltd, Manipal. Here pure gold is processed with the help of various medicinal plants by a patented *Dravyashudh™* technique. The toxicity study (CEFT#3999/08) conducted in Sri Ramachandra Institute Chennai states. The test substance *Hiranyaprash™* falls in Category- 5 in the Globally Harmonised System (GHS), the hazard category defined by: 2000 mg/kg < LD₅₀ < 5000mg/kg. The animal experimentation conducted in Sri Ramachandra Institute Chennai to see immunostimulant property (CEFT#1009/10) found

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to possess the potent immunostimulatory effect on male swiss albino mice when administered at the dose level of 50mg/kg b.wt.

Randomly 104 children were selected for the clinical observation from the population those who are taking Hiranyaprash™. Around 6000 to 8000 children are administered Hiranyaprash™ every month in Muniyal institute of Ayurveda Medical Sciences and Hospital, Manipal, various centres, hospitals and clinics.

Aim and objective of the study:

- To see the efficacy of Hiranyaprash™ in preventing disorder in children.
- To see efficacy of Hiranyaprash™ in reducing the disease frequency in children.

Source for study:

- OPD Kaumarabhritya, MIAMS, Manipal.
- MIAMS KutumbaSadasya Clinics.

Sample Size:

- 104 children undergoing Hiranyaprash™ were included in the study.

Design of Study:

- Single group

Drug:

- Hiranyaprash™ is the patent drug of Muniyal Pharmacy, Manipal of 20ml packing.

Dose of Hiranyaprash™:

- 2 drops for age below 5 years and 4 drops for age above 5 years.

Methodology

Inclusion criteria:

- Children who have undergone 6 consecutive Hiranyaprash™
- Children who have taken only Hiranyaprash™.
- Children under the age of 16 years.

Exclusion criteria:

- Children who have not been administered 6 doses of Hiranyaprash™
- Children who have administered other than Hiranyaprash™ for SwarnaPrashana.
- Children who lapse the dose of Hiranyaprash™.

Assessment criteria:

Following manifestations are observed for assessments-

- Respiratory system
- Common cold
- Sneezing
- Cough
- Breathing difficulty
- Head ache
- Fever
- Gastro Intestinal System
- Loss of appetite
- Distension of abdomen
- Vomiting
- Loose stools
- Hard stools
- Abdominal pain
- Mucus with stools
- Developmental problems

All these 1st, 2nd and 3rd criteria were graded under the following uniform scoring pattern.

- Always -4
- Frequently- 3
- Occasionally- 2
- Not Present- 1
- Absent- 0

Scholastic work performances.

Behavioral Adjustments with classmates.

Behavioral Adjustments with teachers.

Behavioral Adjustments with parents.

Subject understanding ability.

All these 4th, 5th, 6th, 7th and 8th criteria were graded under the following uniform scoring pattern.

- Poor- 01
- Moderate- 02
- Excellent- 03

The data are put in the master chart which has all information of 104 children and analyzed statistically using various tests

OBSERVATIONS

Following observations are found from 104 children undergone Hiranyaprash™.

58 (55.77%) children were below the age of 5 years and 46 (44.23%) children were above 5 years of age. Sex ratio showed male children were 55 (52.88%) and female children were 49 (47.12%) in number. In majority cases i.e, 63 (60.58%) cases it was observed that mother was the informant.

80 (76.92%) children mentioned the Hiranyaprash™ is sweeter in taste. This indicates the palatability of the drug. The drug had no refusal for administration in 103 (99.04%) children. 59 (56.73%) children were school going children.

Table 1: Showing Age groups of children in the study.

S. No.	Age	No. of children	%
1	Below 5 years	58	55.77
2	Above 5 years	46	44.23

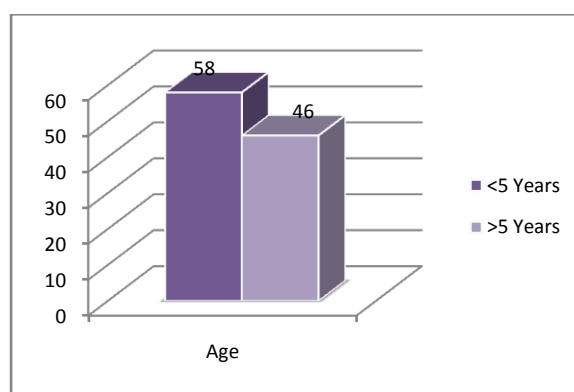


Figure 1: Showing Age groups of children in the study

Table 2: Showing sex ratio.

S. No.	Sex	No. of children	%
1	Male	55	52.88
2	Female	49	47.12

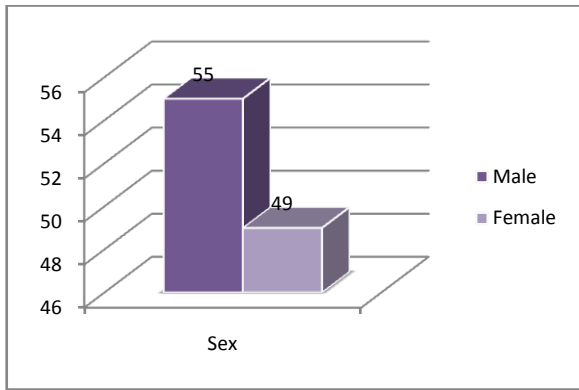


Figure 2: Showing sex ratio

Table 3: Showing percentage of Informant who filled the survey forms of Hiranyaprash™ clinical survey

S. No.	Informant	Number	%
1	Father	37	35.58
2	Mother	63	60.58
3	Sister	2	01.92
4	Aunt	2	01.92

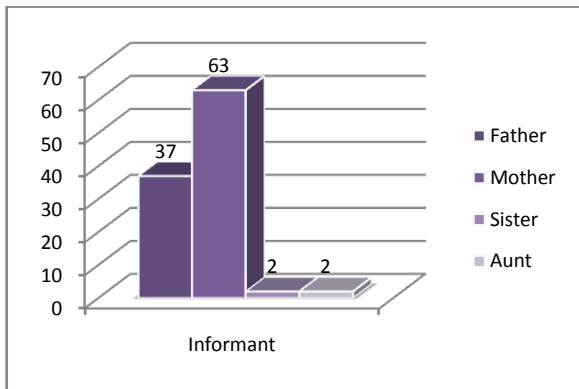


Figure 3: Showing percentage of Informant who filled the survey forms of Hiranyaprash™ clinical survey.

Table 4: Showing the taste of Hiranyaprash™ as stated by the Child

S. No.	Taste	No. of children	%
1	Sweet	80	76.92
2	Bitter	1	00.96
3	Not Mentioned	23	22.12

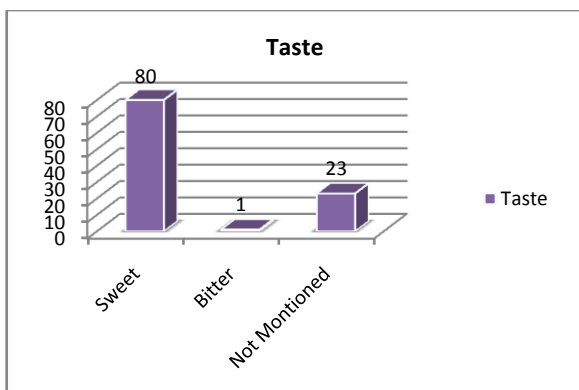


Figure 4: Showing the taste of Hiranyaprash™ as stated by the Child.

Table 5: Showing the refusal for Hiranyaprash™ administration

S. No.	Refusal	Number	%
1	Yes	1	00.96
2	No	103	99.04

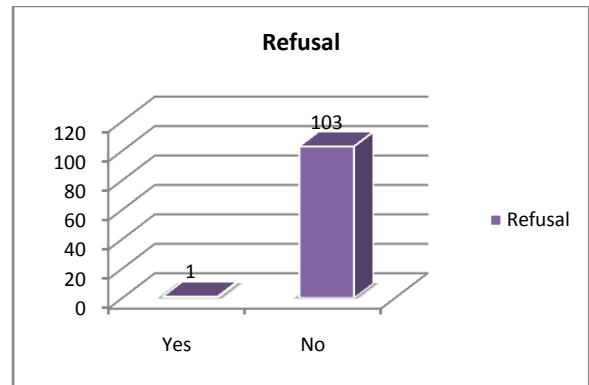


Figure 5: Showing the refusal for Hiranyaprash™ administration

Table 6: Showing the no. of children school going or not

S. No.	School going	Number	%
1	Yes	59	56.73
2	No	45	43.27

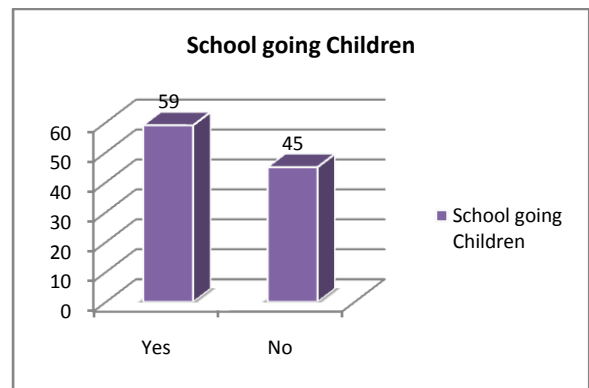


Figure 6: Showing the no. of children school going or not

RESULTS

In the study 104 children's data was analyzed statistically and following results were obtained. Data Before administration of Hiranyaprash™ and the data obtained from the clinical survey are analyzed by applying paired t tests on different parameters of respiratory system, GIT and behavioral parameters.

Analysis of data on Respiratory system manifestations shows high statistical significance for all parameters- cold, sneezing, head ache, cough, dyspnea and fever (Table 7).

Table 8 shows reduction in the occurrence of respiratory manifestations by the administration of Hiranyaprash™.

Analysis of data on GIT manifestations shows (Table 9) high statistical significance in the parameter loss of appetite; moderate significance in the parameters distension of abdomen and abdominal pain; statistical insignificance in parameters vomiting, hard stools, loose stools, mucus with stools.

Table 10 shows reduction in the occurrence of GIT manifestations by the administration of Hiranyaprash™.

subject understanding ability, moderate significance in the parameter behavioral adjustments with classmates, statistical insignificance in the parameters behavioral adjustment with teacher and parents.

Analysis of data on behavioral assessments shows (Table 11) high statistical significance in parameter school work performance and

Table 7: Showing the analysis of data on Respiratory system manifestations.

S. No.	Parameter	n	Mean	SD	SE	't' Value	df	P Value
1	Cold	87	0.7701	1.0081	1.1081	7.125	86	<0.001
2	Sneezing	58	0.7586	1.0141	0.1332	5.697	57	<0.001
3	Head ache	43	0.3488	0.6504	0.0992	3.517	42	<0.001
4	Cough	77	0.7922	1.0555	0.1203	6.586	76	<0.001
5	Dyspnoea	41	0.4390	0.8381	0.1309	3.354	40	<0.001
6	Fever	69	0.8116	0.9436	0.1136	7.144	68	<0.001

Table 8: Showing the analysis of no. of children with respiratory symptoms

S. No.	Parameter	No. of children having symptoms	
		Before administration of Hiranyaprash™	On the Date of Survey
1	Cold	87	73
2	Sneezing	58	50
3	Head ache	43	38
4	Cough	77	66
5	Dyspnoea	41	36
6	Fever	69	55

Table 9: Showing of analysis of data on GIT manifestations

S. No.	Parameter	n	Mean	SD	SE	't' Value	df	P Value
1	Loss of appetite	75	0.4267	1.0157	0.1173	3.638	74	<0.001
2	Distension of abdomen	42	0.2857	0.8050	0.1242	2.300	41	<0.05
3	Abdominal pain	54	0.4444	1.1438	0.1556	2.855	53	<0.01
4	Vomiting	47	0.1702	0.8423	0.1229	1.385	46	>0.05
5	Hard stools	43	0.1163	0.6252	0.0953	1.220	42	>0.1
6	Loose stools	43	0.1163	0.5859	0.0894	1.301	42	>0.1
7	Mucus with stools	43	0.2558	0.8478	0.1293	1.979	42	>0.05

Table 10: Showing the analysis of no. of children with GIT symptoms

S. No.	Parameter	No. of children	
		Before administration of Hiranyaprash™	On the Date Survey
1	Loss of appetite	75	66
2	Distension of abdomen	42	36
3	Abdominal pain	54	46
4	Vomiting	47	42
5	Hard stools	43	40
6	Loose stools	43	38
7	Mucus with stools	43	39

Table 11: Showing the analysis of data on behavioral assessments

S. No.	Parameter	n	Mean	SD	SE	't' Value	df	P Value
1	School work performances	56	0.1786	0.4309	0.0576	3.101	55	<0.005
2	Behavioural adjustments with classmates	56	0.1071	0.3121	0.0417	2.569	55	<0.02
3	Behavioural adjustments with teacher	56	0.071	0.3223	0.0431	1.658	55	>0.1
4	Behavioural adjustments with parents	56	0.018	0.3010	0.0402	0.444	55	>0.1
5	Subject understanding ability	56	0.1786	0.3865	0.0516	3.458	55	<0.001

DISCUSSION

Effect of Swarnabhasma and Gold preparations

Swarnabhasma is time tested in Indian system of Medicine with a praiseworthy therapeutic efficacy. Even the utensils of gold were also

in practice in ancient times with the view of prevention of disease. Now it has been established that Swarnabhasma is of Nano particle size and remains mostly in the form of mono atomic gold^[8].

The Swarnabhasma and gold preparations are established as having efficacy as nootropic activity⁹. The *Swarnabhasma* has been

scientifically found effective as free-radical scavenging activity¹⁰ inflammatory diseases, asthma, respiratory illnesses and immunological disorders^{[11], [12], [13]}.

Honey an essential ingredient of Hiranyspraash™ has been reported to be as an anti-microbial agent^[14], effective in gastrointestinal disorders, in healing of wounds and burns, and to provide gastric protection against acute and chronic gastric lesions^[15]. Honey used as a vehicle here is described as *Yogavahi* in Ayurveda. It acts as a bioenhancer. This further helped in enhancing the efficacy of Hiranyspraash™

Effect of Hiranyspraash™

The drug Hiranyspraash™ is found safe and immunostimulant by the experimental studies carried out in Sri Ramachandra Institute, Chennai.

Analysis of data on Respiratory system manifestations shows high statistical significance for all parameters- cold, sneezing, head ache, cough, dyspnea and fever. Hiranyspraash™ is very much beneficial in reducing the symptoms of respiratory manifestations. Hiranyspraash™ is beneficial in preventing the respiratory manifestations, hence it can be concluded that Hiranyspraash™ increases the immunity of the child. This is due to action of Gold in enhancing the nonspecific immunity and action over the inflammation of respiratory system mucosa.

Analysis of data on GIT manifestations shows high statistical significance in the parameter loss of appetite; moderate significance in the parameters distension of abdomen and abdominal pain; statistical insignificance in parameters vomiting, hard stools, loose stools, mucus with stools. Hiranyspraash™ is beneficial in increasing the appetite of children.

Analysis of data on behavioral assessments shows high statistical significance in parameter school work performance and subject understanding ability, Moderate significance in the parameter behavioral adjustments with classmates, statistical insignificance in the parameters behavioral adjustment with teacher and parents. Hiranyspraash™ is beneficial in increasing the intelligence; thinking ability, subject understanding ability. Hiranyspraash™ acts as MedhyaRasayana. The Swarnabhasma has the nootropic property by which the cognitive and behavioral functions are found with significant changes.

CONCLUSION

Hiranyspraash™ is beneficial in enhancement of physical and mental health of children. It is found that the drug is beneficial in enhancing the immunity of the child. The drug found safe to use. The results found significant in the prevention and control of respiratory, GIT, and behavioral parameters. Further studies are required in the analysis of effect on IQ, Immunological status and different disorders of children.

FINANCIAL SUPPORT

Nil.

CONFLICTS OF INTEREST

None declared.

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