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Role of Samangadi Ghrita Lehana as a Nutritional Supplement for Healthy Growth and Development of Children: A Clinical Study

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ABSTRACT

Children are vulnerable to hamper their growth and development, especially in poverty and source poor setting like India. When one speaks of under-five ailments, about 34% conditions are related to growth, and therefore it is need of hour to do research on ayurveda nutritional supplements to promote the healthy growth and development of children. In kashyapa samhita, there are number of medicated ghee preparation explained, which should be licked with madhu. Samangadi ghrita is one among the enlisted ghrita preparations. Lehana is one of the unique pediatric treatment preparations having therapeutic as well as nutritional value. The main ingredients of lehana are ghrita and madhu which are basically the food substances which are in daily use. Both of these have good calorie and nutritional value which is essential for the growth of the child. Kashyapa samhita the authentic and ancient text of kaumarbhritya has described in details about the lehana in children with due indications and contra indications. Acharya kashyapa has mentioned different ghrita or ghee medicated with the different herbs for the lehana purpose. Different medicated ghee has different indications and has diverse actions on different developing organs as well as developing and growing systems of children. Samangadi ghrita is one of the lehana herbal medicated ghee described in kashyapa samhita in lehadhyaya.

Keywords: Kashyapa samhita; Samangadi ghrita; Kaumarbhritya; Lehadhyaya

INTRODUCTION

Kaumarbhritya is a branch of ayurveda that deals with child rearing, child growth and development, breast feeding practices, treatment of diseases caused by vitiated breast milk, purification of breast milk and the treatment of other childhood diseases. Kashyapa samhita is the ancient territory of kaumarbhritya which is considered as authentic and scientific. Acharya kashyapa has mentioned different classical ayurveda child rearing practices, lehana and childhood samskara in detailed throughout the text. In addition, kashyapa has mentioned the age classification and dosages according to age of child and panchakarma and diet to be followed by child for healthy growth and development. Acharya kashyapa has described the care of the child right from the gestational age during pregnancy, during labor and after the birth up to the age of sixteen years of life. If one closely observed the chapters of kashyapa samhita keenly, one can find one central theme behind all the principles of ayurveda practices. That central theme is the growth of baby. All the samskara, child rearing measures and treatment protocols focusing on the growth of baby, and planned

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systematically without hampering or altering the growth of the child. The growth is narrated as vriddhi in ayurveda. Samskara is the procedure done intentionally at particular age of the human life to achieve particular goal. Considering the changes in human body at specific age samskaras are planned accordingly. Human little one attains the different milestone and maturity as the age advances. Samskara helps to achieve those milestones with ease and in appropriate manner. In ancient time there was impact of the religious conviction, religious teacher and leader. Therefore, samskara were also described in terms of the sacred practices and customs. Over period of time samskara became the ritual traditions. Unless the people were influenced with some religious cause, they were not going to follow the tradition. Hence one will find samskara as more religious than scientific while reading through the sacred books. But when one closely studies the concept and procedures of samskara with the outlook of ayurveda, one can find its scientific backgrounds. Literally lehana means to lick. 'lihyate anen iti lehyam' the substance which licked easily by young infants is called as lehana. Acharya kashyapa mentioned lehana in details with due indications and contraindications [1].

Clinical Study

The clinical interventional trials are of paramount importance in the field of medical sciences, as the data generated by appropriate clinical trial is the most reliable evidence for further use of the formulation in human population. So, a carefully and ethically designed clinical trial is the best and ultimate way of testing a drug for human use. Research is defined as human activity based on intellectual application in the investigation of matter. The primary aim for applied research is discovering, interpreting, and development of methods and systems for the advancement of human knowledge on a wide variety of scientific matters of our world and the universe. The materials and methods used in a scientific research should be substantiated on the basis of the methodology, which determines its validity. The methodology is the rationale that is employed in selecting the materials and methods in order to make the study a dependable one to derive conclusions. Thus, methodology of research includes various research methods as well as the logic behind the methods we use in our research study and explain why we are using a particular method or technique.

Reason to Select the Proposed Research Design

The method of the study was interventional randomized parallel group, active controlled clinical trial. Children eligible for the trials were identified and baseline assessments were performed before randomization. Randomized Controlled Trials (RCTs) are characterized by prospective assignment of subjects, through a random method in to an intervention group and comparator group and are followed for the outcome of interest. Randomized Controlled Trials (RCTs) are generally accepted as the most valid method for determining the efficacy of a therapeutic intervention, because the biases associated with other experimental designs can be avoided. Randomization is the most reliable method ensuring all the members of the population an equal chance of being selected. RCTs are study in which people are allocated at random (by chance alone) to receive one of the clinical interventions. One of these interventions is the standard of comparison. The standard of comparison may be a standard practice, a placebo, or no intervention at all. RCTs seek to measure and compare the outcomes after the participants receive the interventions. It ensures that all the participants in both the groups are similar as far as possible with respect to all known and unknown factors, which might affect the outcome. In order to know the efficacy of trial drug, therapeutic trials were conducted by comparison with standard control. So, in this study an attempt was made to evaluate the efficacy of samangadi ghrita in the healthy growth of children [2].

Hypothesis

Null hypothesis (H_0): Samangadi ghrita lehana is not effective in the healthy growth and development of children of 3 to 6 years of age.

Alternate hypothesis (H_1): Samangadi ghrita lehana is effective in the healthy growth and development of children of 3 years to 6 years of age.

Aim: To study the effect of "samangadi ghrita lehana" in comparison with volunteer without medication.

Objectives

- To evaluate the role of 'samangadi ghrita' in the healthy growth and development of children.
- To compare it with the children observed without medicinal course (Table 1).

Table 1: Outcomes of the clinical study.

Outcome	Achievement	Time points
Primary outcome	Weight gain	4 weeks-5 Weeks
	Improvement in MUAC	6 weeks-10 Weeks
	Improvement in height	10 weeks-12 weeks

Secondary outcome	To maintain the healthy growth	12 weeks
	To prevent growth ailments	12 weeks
	To maintain the QOL of children	12 weeks

MATERIALS AND METHODS

Study Design

Randomized interventional parallel group, controlled clinical trial.

Selection of patients: The children of either gender, attending OPD of kaumarbhritya department of Parul Ayurved hospital Limda, Vadodara and also from the school health survey (Limda primary and secondary government school and Ishwarpura primary government school) conducted by Parul Ayurveda hospital Limda, Vadodara were registered in the present study duly fulfilling the consent procedures. All details of the children were recorded and maintained in the specially prepared Clinical Research Pro Forma (CRPF).

Research setting: OPD of Kaumarabhritya department, PAH, Limda-Vadodara was selected as the research setting.

Research population: The children between the ages of 3 years to 6 years of either gender attending KB OPD of Parul Ayurved hospital, Limda-Vadodara and government primary school of Limda and Ishvarpura village, were the research population of the study. Biogas was analyzed with a 7890 A gas chromatograph (Agilent, USA) equipped with a thermal conductivity detector, and helium as the carrier biogas. A2 m × 3 mm stainless steel column packed with TDX-01.

Sampling: Simple random sampling was followed in the study. The subjects were selected as per the selection criteria and randomly distributed into intervention and standard control groups. For the random distribution of subjects, electronic digital randomization table was used.

Sampling element: Sampling element was children between the ages of 3 years to 6 years of either gender [3].

Diagnostic Criteria

Inclusion criteria:

- Children between the ages of 3 years to 6 years of either gender.
- Weight less than expected for age between normal to minus 2 SD.
- Children with good appetite.
- Children not sleeping adequate in night.
- Children with scanty urination.
- Children not passing stool more than 3 days.
- Parents/legal guardians willing to give written informed consent.

Exclusion criteria:

- Children between the ages of less than 3 and more than 6 years of age.
- Children with frequent Indigestion, vomiting and flatulence.
- Children with fever, diarrhea, jaundice, anemia
- Children with pneumonia, RDS, cough
- Children with infectious diseases such as hepatitis, allergic diseases, other metabolic diseases/errors, endocrine diseases, genetic anomalies.

Grouping of patients:

- Group A-children administered with samangadi ghrita.
- Group B-children under observation without any drug or procedure.

Trial drug: Samangadi ghrita: Ref: Kashyapa samhita, sutra sthana, lehadhyaya.

Drug and dose schedule:

- Dose: 4.5 g to 9 g samangadi ghrita for oral administration twice a day empty stomach.
- Duration of the therapy-10 weeks.
- Duration of follow up-12 weeks.

Investigations:

- Complete Blood Count (CBC)
- Sr. total protein
- Sr. albumin
- Sr. calcium (in selected cases)

Adverse Drug Reactions (ADRs): No Adverse Drug Reaction (ADR) were duly recorded and reported throughout the clinical trial.

Follow up: 12 weeks (2 weeks after the completion of therapy)

The assessment was based on the following parameters.

Primary parameters: All the anthropometrical parameters were assessed on the basis of growth chart monitoring guidelines of WHO.

- Weight
- Height
- Mid Upper Arm Circumference (MUAC)
- Chest Circumference (CC)
- Head Circumference (HC)

Secondary parameters:

- Improvement in QoL
- Improvement in serum protein, albumin and calcium levels

Assessment of total effect of therapy:

- Cured/excellent response: 100% relief of signs and symptoms
- Markedly improved: Improvement between>75%-99%
- Moderately improved: Improvement between>50%-75%
- Mildly improved: Improvement between 25%-50%
- Unchanged: No relief in signs and symptoms

Presentation of data: The effect of treatment was tested for statistical significance by using appropriate statistical tests. The effect of treatment of both trial and standard control group on clinical features and laboratory parameters was tested for statistical significance with the help of paired student's 't' test between the scores obtained before and after treatment within a group. The effectiveness of the two effect of therapy of both the groups (intervention and standard control) was compared by using unpaired student's 't' test between the results of two groups under trial.

After obtaining 't' value the corresponding 'P' value against particular degree of freedom was noted on the 'Table of 't''. P-value<0.05 was considered as statistically significant, P<0.01 or P<0.001 were considered as highly significant (Table 2).

Table 2: Status of clinical study.

Patients	Trial group (Group A) Samangadi ghrita	Standard control (Group B) Observational	Total
Registered	22	20	42
Completed	22	20	42
Drop out	-	-	-

Total 42 children were registered in the clinical trial. Out of 42 children 22 were enrolled in the trial group (Samangadi ghrita lehana) and 20 were enrolled in the standard control group (observational). Total 42 children completed the course of treatment and follow up; 22 children in trial group and 20 children in the standard control group. No any volunteer dropped out from the study.

Observation showed that, anthropometrical parameters like weight, height, and Mid Upper Arm Circumference (MUAC) shows statistically significant (p<0.001) results; while Chest Circumference (CC), Head Circumference (HC), and Body Mass Index (BMI) showed statistically significant improvement (p<0.05) in samangadi ghrita lehana treated group children (Table 3).

RESULTS

The statistical analysis of subjective parameter of group-A (Samangadi ghrita lehana) within group assessment.

Table 3: Anthropometry: Group A.

Parameters	N	BT-value	AT-value	SD	SE	t-value	p-value	Significant
Weight	22	12.91	13.98	0.78	0.17	5.83	<0.001	HS
Height	22	104	104	1.33	0.28	6.91	<0.001	HS
Head circumference	22	47.25	47.45	0.37	0.08	2.61	<0.05	S
Chest circumference	22	47.71	50.93	6.36	1.36	2.38	<0.05	S
MUAC	22	14.14	15.25	0.79	0.17	6.65	<0.001	HS
BMI	16	11.79	12.34	0.76	0.19	2.95	<0.05	S
QOL	22	3.1	3.85	0.07	0.014	-36.6	<0.001	HS

The statistical analyses of hematological parameters of group-A (Samangadi ghrita lehana) within group assessment. Observation showed that, hematological parameters like Hb, platelet, and serum albumin levels shows statistically significant (p<0.001) results; while serum calcium level, showed statistically significant improvement (p<0.05) in Samangadi ghrita lehana treated group children. And there is no statistically significant (p>0.05) result in the RBCs, Total Leucocyte Count (TLC) and serum total protein levels (Table 4).

Table 4: Hematological parameters: Group A.

Parameters	N	BT-value	AT-value	SD	SE	t-value	p-value	Significant
Hb%	14	9.71	11.25	0.8	0.22	7.14	<0.001	HS
TLC	14	9028.5	7507.2	3102.1	829.1	1.83	>0.05	NS
RBC	14	4.75	4.6	0.65	0.17	0.84	>0.05	NS
Platelet	14	564533	499200	45701	11800	5.5	<0.001	HS
Total protein	14	8.86	9.56	1.9	0.5	1.4	>0.05	NS
Albumin	14	3.43	4.7	0.7	0.2	6.9	<0.001	HS
Sr. Calcium	8	9.01	9.8	0.44	0.16	4.22	<0.01	S

The statistical analysis of subjective parameter of group-B (observational volunteers) within group assessment. Observation showed that, anthropometrical parameters like weight and Chest Circumference (CC) shows statistically highly significant ($p<0.001$) results; while, height and Mid Upper Arm Circumference (MUAC) showed statistically significant improvement ($p<0.05$) in observational volunteer group children [4]. Head Circumference (HC) and Body Mass Index (BMI) showed no statistically significant ($p>0.05$) changes in observational volunteer group children. Also statistically significant ($p<0.001$) results on QOL (Quality of Life) parameters in children observed without medicine (Table 5).

Table 5: Anthropometry: Group B.

Parameters	N	BT-value	AT-value	SD	SE	t-value	p-value	Significant
Weight	20	13.5	14.07	0.52	0.12	4.4	<0.001	S
Height	20	104.15	104.55	0.8	0.18	2.18	<0.05	S
Head circumference	20	47.8	47.97	0.5	0.1	1.58	>0.05	NS
Chest circumference	20	49.25	50.25	0.97	0.22	4.5	<0.001	S
MUAC	20	14.2	14.6	0.6	0.12	3.59	<0.01	S
BMI	16	12.02	12.54	0.67	0.17	2.03	>0.05	NS
QOL	20	3.13	3.4	0.32	0.07	3.94	<0.001	S

The above table reveals the statistical analysis of hematological parameters of group B (observational volunteers) within group assessment. Observation showed that, hematological parameters like Hb and serum albumin levels shows statistically highly significant ($p<0.001$) results; while platelet and Total Leucocyte Count (TLC) showed statistically significant improvement ($p<0.05$) in observational volunteer group children. And there is no statistically significant ($p>0.05$) result in the RBCs, and serum total protein and serum calcium levels of the group-B children (Table 6).

Table 6: Hematological parameters: Group B.

Parameters	N	BT-value	AT-value	SD	SE	t-value	p-value	Significant
Hb%	13	9.33	10.6	0.95	0.26	4.96	<0.001	S
TLC	13	8500	6946	2409	668.2	2.32	<0.05	S
RBC	13	4.99	4.95	0.65	0.18	0.19	>0.05	NS
Platelet	13	325153	228307	1023010	28375	3.4	<0.01	S
Total protein	16	9.5	9.9	1.02	0.25	1.45	>0.05	NS

Albumin	16	3.38	4.2	0.49	0.12	7.93	<0.001	S
Calcium	4	9.2	9.9	0.36	0.2	3.36	>0.05	NS

The above table reveals the comparative statistical analysis of anthropometrical parameters of group-A (Samangadi avaleha) and group-B (observational group). Observation showed that, among these results on anthropometrical parameters chest circumference, height, mid upper arm circumference and Quality of Life (QOL) shows statistically highly significant results while head circumference Body Mass Index (BMI) and weight shows statistically non-significant results (Table 7).

Table 7: Anthropometry comparison.

Parameters	Df	Mean		Mean difference	t-value	p-value	Significant
		Gr A	Gr B				
Weight	40	0.97	0.52	0.45	2.15	>0.01	NS
Height	40	1.95	0.4	1.5	1.5	<0.01	S
Head circumference	40	0.205	0.175	0.02	0.2	>0.01	NS
Chest circumference	40	1.86	1	0.86	3.19	<0.01	S
MUAC	40	1.11	0.45	0.664	3.12	<0.01	S
BMI	40	0.42	0.27	0.15	0.74	>0.01	NS
QOL	40	0.75	0.28	0.4	6.72	<0.01	S

The comparative statistical analysis of hematological parameters of group-A (Samangadi avaleha) and group-B (observational group). Observation showed that, Hb%, TLC, RBC count, platelet and serum protein parameters were found statistically non-significant during the statistical comparison of both the groups. While total serum albumin and serum calcium level comparison was found statistically significant (Table 8).

Table 8: Hematological parameters comparison.

Parameters	Df	Mean		Mean difference	t-value	p-value	Significant
		Gr A	Gr B				
Hb%	22	1.53	1.3	0.23	0.7	>0.01	NS
TLC	22	63	25	38	0.4	>0.01	NS
RBC	22	0.5	0.3	0.17	0.28	>0.01	NS
Platelet	22	6352	68857	62504	1.25	>0.01	NS
Total protein	16	2.07	0.37	1.7	1.53		NS
Albumin	16	3.01	0.98	2.1	2.64	<0.01	S
Calcium	4	0.54	0.7	0.24	3.63	<0.01	S

DISCUSSION

Results obtained in this clinical trial showed statistically significant improvement in both groups. Though there are statistically significant results in children observed without treatment, the percentage increase was more in children treated with samangadi ghrita lehana group [5-7]. In addition, the statistical comparison of the result obtained from both the groups shows significant results. From this finding it is very clear that, samangadi ghrita lehana shows better improvement in the growth anthropometrical parameters, compare to the anthropometrical findings of the children observed without medicine. Lehana kalpana serves both the objectives of correction of metabolism as well as the supplements. The ingredients of samangadi ghrita are uniquely combined and have digestive, carminative, non tropic, healing properties ultimately improves the physical bulk and strength of child. Contrary to common belief, only increased use or overloading of food supplements is not enough to improve the growth of child. At the same time corrective measures to improve absorption, digestion and assimilation is very essential so that, there is optimum output with the use of supplements [8].

In all there are three prerequisites of healthy growth and development:

- Adequate nutrients or food stuff

- Proper digestion and metabolism
- Supplements of additional nutrients

Adequate nutrients or food stuff: The diet of the children observed in this study was found to be adequate in calorie value as well as nutrients; all the children of anganwadi and primary school were supplied with food items with adequate calorie and nutritional value.

Proper digestion and metabolism: Main etiological factor observed in studied population which alter or hampers the digestion is adhyashana and vishamashana, also the increased use of food with monotonous rasa or guna was also one of the etiological factors in studied children. Use of road side junk food stuff, chocolates, ice-creams and cold drinks were some food stuff in diet. All above mentioned food and food habits hampers the digestion and metabolism of children affecting their healthy growth and development.

Supplements of additional nutrients: From above discussion it is clear that, though there is adequate diet and food, there is suboptimal growth of the children and hence administration of the supplements containing the drugs which improves the metabolism is important step to correct the metabolism and maintain the healthy growth. During trial assessment, it was observed that there is systematic improvement in the agni, abhyavaharana, bala and bhara in consequent visits. It suggest there is stepwise improvement, in agni, rasa dhatu and later on chronological improvement of next dhatu like rakta, mamsa, meda, asthi, majja, and oja and hence there is stepwise systematic improvement observed in agni, abhyavharana, bala and bhara, simultaneously improvement in pramana *i.e.,* Chest Circumference (CC) and Mid upper Arm Circumstance (MUAC). At last to summarize the effect of samangadi ghrita on healthy growth and development of children, it very clearly explained in conceptual study that, ghrita and madhu are sweet in taste, easy to digest and assimilates, having good palatability due to sweet taste and semisolid consistency, also have yogvahi property means it carries the active ingredients and metabolites of the drugs used along with them to target organs. Therefore, drugs easily cross the Blood Brain Barrier (BBB), and at the same time the ingredients of samangadi ghrita have antioxidant properties, relieve oxidative stress on cells and tissues, improves metabolism and helps to grow and repair all body tissues. At the same time the ingredients supply good nutrients including vitamin C and therefore useful to improve physical bulk and strength of the baby [9,10].

CONCLUSION

Kaumarbhritya is an ever changing field which requires continuous updating and today all the principles of lehana are coming into limelight and evidenced with modern research parameters. In ayurveda growth and development is thoroughly explained in the classics as samvardhana and samskara respectively. All the principles and procedures of samvardhana, samskara and lehana are scientific, time tested, safe and it is a standard palatable treatment to aid the healthy growth and development of children. This shows the wisdom of ayurveda in the field of growth and development and demanding better research strategies from kaumarbhritya vid for mainstreaming the ayurveda principles of growth and development with today's modern child rearing practices. The present study highlights the importance and significance of lehana with samangadi ghrita in comparison to the observational group children without medication. There are certain nutritional supplementary drug and diet mentioned in Ayurveda for the healthy growth and development of children. Considering the palatability and nutritional as well as therapeutic values of samangadi ghrita, it is one of the best formulations for healthy growth of children. Pharmaceutical and quality control testing of samangadi ghrita showed all standard reading in accordance with quality control standard parameters and therefore suggestive of authenticate preparation without saponification and rancidity with good shelf life. Observations and results obtained from the clinical study showed statistically significant improvement in anthropometrical parameters. There are no complications or illness during follow up period in the children treated with the samangadi ghrita.

ETHICAL CONSIDERATIONS

The formulation in the proposed study is a classical time tested ayurvedic drug. The formulation has no known toxic/ adverse effects in the prescribed dose. Being classical ayurvedic formulation, it cannot be considered necessary to have animal trials as per the standard ASU drug guidelines. An informed consent was obtained from the parents before recruiting the children into the trial. Autonomy of the participants was given utmost respect and was allowed to have interventions for any acute episodes of other associations or to opt out of the study at any time.

ETHICAL CLEARANCE

This trial has been cleared by Institutional Ethics Committee (IEC).

Vide: Ref-PU/PIA/IECHR/2017 126; approved on: 10th April 2017.

CTRI REGISTRATION

The present clinical trial has been registered in Clinical Trials Registry India (CTRI). The registration number is CTRI/ 2018/01/011468; registered on: 22/01/2018 trial registered retrospectively.

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