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ORA- Study Protocol

EFFICACY OF *ASHWAGANDHADI LEHA* GRANULES IN COMPARISON TO HYDERABAD MIX ON *KARSHYA*, UNDERNUTRITION IAP GRADE I AND II IN CHILDREN – A DOUBLE BLIND RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT :

Introduction: *Apatarpanajanya vyadhi* with *krushata* (wasting) as a cardinal feature is Karshya and is correlated with under nutrition. Underweight prevalence has decreased from 35.8% to 32.1% (NFHS 5 report). Despite various programmes like *Akshaya patra*, *Rashtriya Bala Swasthya Karyakram* to curb under nutrition, the results not satisfactory. Thus, WHO and GOI prioritize malnutrition research with emphasis on traditional food recipes. Researches on formulations like *Drakshadi Gritha, Ashwagandha* Granules and *Prinan Modaka, Balya* Biscuit and *Kooshmanda avaleha* mostly exploratory with few being controlled clinical trials. Studies using z scores assessment on WHO growth charts. *Ashwagandhadi leha* mentioned in *Sahasrayogam – Lehya Prakarana* indicated in *Karshya* possesses *Balya* property. Difficulties with administration of ghrita, leha yoga were due to the texture, smell or taste of. Thus, a pharmaceutically modified *Ashwagandhadi leha* granules was proposed for research. This is expected to be wholesome combination by virtue of its ingredients that cover the calorie, proteins, fat and calcium needs of the child along with pepper to enhance bio availability and immunity. Thus, the present study intends to evaluate the effect of Ashwagandhadi leha granules on Karshya, undernutrition IAP grade I and II. MATERIALS AND **Methods**: This is a prospective, close-label, double blind randomized controlled clinical trial of total 40 participants diagnosed with *Karshya*, Undernutrition IAP grade I and II. **Trial group** subjects will receive for age group 2 to 4 years it will be 15g and for age group 5 to 6 years it will be 20g of *Ashwagandhadi leha* granules with 100ml milk BD orally, after food for 90 days. **Control Group** subjects will receive Hyderabad Mix in the similar way. **Discussion**: The study is expected to show that the intervention of *Ashwagandhadi leha* granules is as effective as Hyderabad Mix in managing *Karshya*, Undernutrition IAP grade I and II.

KEYWORDS: *Karshya*, Undernutrition, *Apatarpanajanya Vyadhi, Ashwagandhadi leha granules*

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1. INTRODUCTION

Karshya is one among disease which comes under *Apatarpanajanya vyadhi* which presents the krushata as a cardinal feature of wasting. It is a nutritional disorder, which can be correlated with undernutrition. [1-2]

Undernutrition is a condition in which there is inadequate consumption, poor absorption or excessive loss of nutrients. The term malnutrition encompasses both undernutrition as well as over nutrition. However, sometimes malnutrition and protein energy malnutrition (PEM) are used interchangeably with undernutrition.[3] The estimated number of underweight, malnourished and severely malnourished children under 5 years of age is obtained under National Family Health Survey (NFHS) conducted by the Ministry of Health & Family Welfare. As per the recent report of NFHS-5 (2019-21), the nutrition indicators for children under 5 years have improved as compared with NFHS-4 (2015-16). Stunting has reduced from 38.4% to 35.5%, Wasting has reduced from 21.0% to 19.3% and Underweight prevalence has reduced from 35.8% to 32.1%.[4] In Karnataka, the prevalence of underweight among under-five children was 33% and stunting 35%.[5] Despite having economic growth, progress and largest food and nutrition program, India is home to over one-third of world's malnourished children, and for 5.6 million deaths due to malnutrition out of 10.4 million child deaths per year. Underweight children fail to maintain natural body capacities such as growth, resisting power to infections as well as recovering from disease, learning and physical activities. Poor feeding of infants and young children alone is considered as the single most important risk factor for under nutrition and contributes to more than half of the nearly 11 million deaths in each year among children under five.[6] Despite enormous efforts from the government in the form of various nutritional programs as a part of National Health Mission, integrated child development services, *Anganwadi* program, *akshaya patra, poshan maha* and *poshan saptaha, Rashtriya Bala Swasthya Karyakram* to curb under nutrition, the results are minimal and efforts are not converted in to indices. Thus, WHO and government of India keep malnutrition as priority area of research and emphasizes efforts towards incorporating traditional food recipes [7] and practices for improving nutrition in children. There have been various researches on malnutrition and under nutrition using various traditional dietary supplements and Ayurveda formulations like *Drakshadi Gritha*,[8] *Ashwagandhaghrita*,[9] *Amritapraasha Ghrita*,[10] *Paushtika* Biscuit,[11] *Ashwagandha* Granules and *Prinan Modaka*,[12] *Balya* Biscuit and *Prinana Modaka*[13] *Prinan Modak* and *Godhumadi Modak*,[14] *Vidarikandadi Vati* and *Kshirabala Taila Basti*,[15] *Chukkiliratyadi Churna*,[16] *Ashtamangala Gritha*,[17] *Kooshmanda avaleha*[18] and so on. Most of them are exploratory studies; some of them controlled clinical trials with assessment using nutritional anthropometry. Hardly any of them concentrated on assessing nutritional value of the trial drug, calculating the calorie deficit and supplementing the deficit through the supplement. Further, there is lack of studies expressing the results based on standard assessment criteria using z scores on WHO growth charts. There is a need for a

controlled clinical trial that addresses these factors. *Ashwagandhadi leha* mentioned in *Sahastrayogam – Lehya Prakarana* indicated in *Karshya* contains 6 herbs is said to possess properties like *balya* (strength promoting) property.[19] Further, in previous studies it was noted that *ghrita, leha* yoga were though effective in improving the nutritional status, but there was a certain degree of difficulty either in administering calculated dose and in acceptance equally among children either due to the texture, smell or taste of the formulation. Thus, a thought was given to pharmaceutically modify the proposed trial drug namely *Ashwagandhadi leha* into granules so that it can be given as nutritional supplement just like brands namely Horlicks, boost etc which are considered choice of supplements by both parents and children. Further, in this form it is easy to maintain the consistency, dosage and could be appealing to target population. Apart from being safe, effective intervention in the management of Karshya, Ashwagandhadi leha granules is expected to be wholesome combination by virtue of its ingredients that cover the calorie, proteins, fat and calcium needs of the child along with pepper, a celebrated bio availability and immunity enhancer. (undernutrition IAP grade I and II). Thus, the present study intends to evaluate the effect of *Ashwagandhadi* leha granules on *Karshya*, undernutrition IAP grade I and II in a more refined pharmacological and clinical standards in children with *Karshya*.

2. OBJECTIVES:

PRIMARY OBJECTIVE: -

1. To assess the efficacy of Ashwagandhadi leha granules in Karshya, undernutrition IAP grade I and II Children on graded clinical features of Karshya and anthropometry parameters like height, weight, mid arm circumference, BMI, chest circumference, skin fold thickness and on WHO Z score on weight for height.

SECONDARY OBJECTIVES: -

1. To assess the efficacy of *Ashwagandhadi leha* granules in *Karshya*, undernutrition IAP grade I and II on Complete Blood count, Sr. Protein, Sr. Albumin, Sr. lipids, AG Ratio, BUN and Urine routine.
2. To compare the efficacy of *Ashwagandhadi leha* granules and Hyderabad mix in the management of *Karshya*, undernutrition IAP grade I and II in children.
3. To assess the nutritional values of *Ashwagandhadi leha* granules.

Study Design

A Prospective, Close-label, Double blind, Randomized, controlled clinical, parallel groups, equivalance trial. Improvements in graded clinical features of Karshya and anthropometry parameters. Like height, weight, mid arm circumference, BMI, chest circumference, skin fold thickness at 0th ,30th, 60th and 90th day. WHO Z score on weight for height at 0th 90th and 120th day.

Study Setting

Outpatient and inpatient department of Shree Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru.

Study Duration:

Total duration of clinical study is 120 days

Eligibility Criteria

Eligibility criteria: ICD – 10 – E40/46 [20]

Written informed consent shall be taken prior to participating in the study.

Inclusion criteria:

1. Children of age group 2-6 years of either gender who fulfills the diagnostic criteria
2. Children fulfilling IAP classification of malnutrition (Grade I and II)
3. Children fulfilling either 2 to 3 features of *Karshya*.
4. Parents willing to participate their kid and ready to sign assent/consent form consent.

Exclusion criteria:

1. Children suffering from chronic systemic illness, genetic syndromes, hereditary diseases, congenital anomalies, and malignancy
2. Children mal-absorption syndrome or metabolic error
3. Children with malnutrition belonging to Grade III and grade IV

Interventions

Irrespective of the group, children will be given Mebendazole 100 mg BID for 3 days after food for deworming followed by *chitrakadi vati* 1 tid ½ hour before food for 3 days for the purpose of *Deepana* and *pachana*. Following these children in study group will receive for age group 2 to 4 years it will be 15 grams and for age group 5 to 6 years it will be 20 grams of *Ashwagandhadi leha* granules with 100ml milk twice daily for a period of 3 months with food or immediately after food.

Children in control group will receive for age group 2 to 4 years it will be 15 grams and for age group 5 to 6 years it will be 20 grams of Hyderabad mix 100ml milk twice daily for a period of 3 months with food or immediately after food as mentioned above.

The detailed study schedule is described in table 1.

Table 1: Study Schedule

Study event	Baseline	Day 0	Day 30	Day 60	Day 90	Day 120
Baseline assessment anthropometry parameters like height, weight, mid arm circumference, BMI, chest circumference, skin fold thickness.	✓					
Informed consent	✓					
Recruitment	✓					
Demographic profile	✓					
Intervention (90 days)	✓	✓	✓	✓	✓	
Follow-up		✓	✓	✓	✓	✓
Assessment by clinical evaluation	✓	✓	✓	✓	✓	✓
Assessment by evaluation like complete blood	✓				✓	

count, Sr. Protein, Sr. Albumin, Sr. lipids, AG rations, BUN and Urine routine.						
Evaluation using the assessment anthropometry parameters likes height, weight, mid arm circumference, BMI, chest circumference, skin folds thickness.		✓	✓	✓	✓	✓
Drug compliance	✓	✓	✓	✓	✓	✓
Rescue medication (If required)		✓	✓	✓	✓	✓
Assessment of adverse events		✓	✓	✓	✓	✓

Discontinuation/modification criteria: In the event of an emergency, rescue medicines may be administered at the discretion of the Principal Investigator. All such instances must be documented in the appropriate section of the Case Record Form.

Adherence monitoring strategy: Patient advised to keep track of symptoms and report via electronic media.

Outcomes

Primary outcome measure:

Improvements in graded clinical features of Karshya and anthropometry parameters. Like height, weight, mid arm circumference, BMI, chest circumference, skin fold thickness at 0th ,30th, 60th and 90th day. WHO Z score on weight for height at 0th 90th and 120th day.

Secondary outcome measures:

Changes and improvements in Complete Blood Count, S. Protein, S. Albumin, S. Lipids, AG Ratio, BUN and Urine at 0th and 90th day.

Sampling Size:

Sample size calculation using standard deviation from previous study

N = 2(SD)2 x (Z(1-α) +Zβ)2 / d2

Zα=1.96 for 95% confidence level

SD= 3.864 from previous study [21]

Zβ = Power of the study = 0.84, d = 0.5

N = 2 x (3.864)2 x (1.96 + 0.84)2 / (1 - 5)2

= 2 x 14.93 x 7.84 / 16

= 14.53

= 15

Sample size for current study will be 16 in each group

Considering 20% dropouts rate N = n/(1-d) i.e., 4 So, Total = 19

Looking into the feasibility and time constraints, Sample size for current study will be 40

Hence, for the current study, sample size (N) = 40

20 samples in each group will be taken for the present study

Recruitment:

Study group: 20 children under the age group of 2 to 6 years visiting Kaumarbhritya OPD of SDM Bengaluru with features of Karshya will be taken for the study

Control group: 20 children under the age group of 2 to 6 years visiting Kaumarbhritya OPD of SDM Bengaluru with features of Karshya will be taken for the study

Allocation and concealment: Random allocation using computer generated random tickets which will be kept labelled in an Opaque sealed cover, to be opened in front of guide while starting the intervention.

3. METHODS

Current research will be an open-label, double blind, interventional, prospective randomized controlled clinical trial.

Data Collection Method:

Data collection will be carried out with a customized Case Report Form (CRF), and assessments will be done using parameters like, Height, Weight, Mid arm circumference, BMI, Chest circumference, Skin fold thickness and Z Score on weight for height.

Data Management

Specific Case Report Form (CRF) will be used to collect detailed data and later it will be exported to MS Excel and statistical analysis will be done using IBM SPSS Version 26.

Statistical Methods:

For statistical analysis, data will be collected using a specially designed Case Report Form (CRF) encompassing all aspects of the study and compiled into an MS Excel spreadsheet. The data will be tabulated, and analysis will be performed using IBM SPSS Version 26.

Descriptive Statistics:

Base line data will be analysed using descriptive statistics in terms of frequency, percentage, and range. Median and percentages will be used to analyse nominal and ordinal data, while mean and standard deviation for continuous data.

Inferential Statistics:

To infer the clinical study and to draw conclusions Parametric and Non-Parametric tests will be applied accordingly.

Level of Significance: A p-value of <0.05 will be considered statistically significant.

Non-Parametric Tests:

For subjective data, the Wilcoxon Signed-Rank Test will be used to evaluate within-group differences before and after treatment.

The Mann-Whitney U Test will be employed to compare differences between the trial and control groups.

For comparisons involving more than two sets within the same group, Friedman's Test will be applied.

Parametric Tests:

For objective data, the Paired t-test will be used to assess within-group differences before and after treatment.

The Unpaired t-test will be used to compare differences between the trial and control groups.

Categorical Data:

Categorical variables will be analysed using the Chi-Square Test.

Effect Size:

Effect size will be calculated using Cohen's d formula.

Data Monitoring

The researcher and guide will monitor data, ensures adherence to the treatment protocol, tracking adverse effects, and managing participant enrolment.

Auditing: Since it is a small trial external audit is Not applicable.

Adverse Effect Management and Safety Measures

Although there are no anticipated serious side effects, any unexpected events that may come across during the study will be documented and notified to concerned authority. Prior to the study, parents shall be asked to disclose any known food allergies. All significant adverse events will be recorded in final report.

Ethical Issues and Informed Consent

Ethical approval for the trial was obtained from the Institutional Ethics Committee of SDMIAH on May 16, 2024 (Ref: SDMIAH/IEC/57/2024) and was registered in Clinical Trials Registry of India (CTRI) on February 27, 2024 (CTRI/2025/02/081372). The study will adhere to the ethical principles outlined in the Declaration of Helsinki. Written informed consent will be obtained prior to enrollment in to trial. Participation will be entirely voluntary, with the option to withdraw at any point of time. The final trial dataset will be anonymized and accessible only to the primary investigator, designated data auditors, and study supervisor. Patient data will be kept strictly confidential. In the event of any adverse events, appropriate will be provided.

Study Status

Open for recruitment

Dissemination

Upon completion of the trial, a research paper outlining the original findings will be published in an open access indexed journal for publication so as to reach wider scientific population. Further, a structured awareness program will be organized to reach out people in community.

4. DISCUSSION

Undernutrition remains to be priority area of research in India amidst rising concerns of over nutrition and micro nutrient deficiency. There has been emphasis on encompassing traditional and cultural food in order to enhance the outcome in the undernutrition management. This study with a standard control can be potential research on traditional nutritional supplement and if proven efficacious, it can be studied in large scale and adapted at primary care practitioner for community research and later to be at the level of policy making.

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Data collection & literature search: Dr. PN

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Conflict Of Interest - None

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Additional Information:

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