INDEX

Sr. No.	Title	Page
		No.
1.	Introduction	2-3
2.	Need of study	3-4
3.	Review of Literature	4-5
4.	Previous work done	6
5.	Aims & Objectives	7
6.	Aim of study	7
7.	Objectives of study	7
8.	Materials And Methods	7
9.	Source of study:	7
10.	Study Design:	7
11.	Study Type:	7
12.	Sample size:	7
13.	Grouping:	8
14.	Inclusion criteria:	8
15.	Exclusion criteria:	8
16.	Withdrawal criteria	8
17.	Selection of Material:	9
18.	Composition of the Formulations:	9
19.	Safety Profile:	9
20.	Preparation of Formulation:	10
21.	Dosage:	10
22.	Study duration:	10
23.	Follow up Period:	11
24.	Screening Investigations:	11
25.	Specific Investigations:	11
26.	Subjective Parameters:	11
27.	Objective Parameters:	11
28.	Statistical Methods:	13
29.	Assessment of Results:	13
30.	PICO model:	13
31.	References:	15-16

Title-

"Comparative Study on the effect of Ksheerabala Taila Matra Basti and Dhatripayasyadi Ghrita in Karshya"

1]Introduction-

Karshya is a disease in which the body of a person becomes emaciated, mainly due to quantitative and qualitative reduction of Rasa Dhatu, which hampers the nourishment of body. The word krusha is derived from the root 'krushtanukarane' which means Alpa, Sookshma, Ksheena (lean or emaciated). Karshya has been included in Nanatmaj Vata Rog, Rasapradoshaj Rog Apatarpanajanya Vyadhi and the person suffering from Karshya has been entitled as one among Ashtonindit Purush. It is also said that during the time of fetal formation if the proportion of Shukra Dhatu is high and that of Medo Dhatu is low, the child born will be emaciated. Etiology of Karshya has been narrated as intake of Ruksha, Annapana, Langhana, Pramitashana, Vegavidharan, Alpabhojan and Ativyayam . Ayurveda depicts that the root cause of all the diseases is *Mandagni*. In *Karshya* also the status of Agni remains Manda . The child having Mandagni when get exposed to etiological factors of Karshya end up in deterioration of Rasa Dhatu due to which there is uttar-uttar Dhatukshaya . The clinical presentation of Karshya is described as presence of Sushkashroni, Udar and Greeva (emaciated of buttocks, abdomen and neck), Dhamanijala santataha (Prominent venous network in the body) reduce muscles, Twakasthi shisha (remains skin and bones), prominence of joints¹², Sthoola parva (prominent inter-phallengial joints)¹³, inability to withstand *Pipasa* (thrist), *Kshudh* (hunger), extreme climatic conditions like Sheeta, Ushna, Vata, Varsha (cold,heat,wind,rain) and carry heavy weights.

Acharya clarifies that a person suffering from Karshya can be afflicted any Vata Vyadhi and diseases like Pleeha, Kasa, Rajyakshma, Shwas, Arsha and Grahani .The line of management of Karshya explained by Acharya show a multidimensional approach comprising of both external and internal therapy along with modification in diet and life

style. Both external and internal *Snehan* usage of *Vrushya* and *Laghu Santarpana* drugs are few of them.

In contemporary science *Karshya* can be understood as the clinical entity, under nutrition. This is a condition in which there is insufficient food intake and repeated, poor absorption or deficient in vitamins and minerals ¹⁸. As per WHO classification there are two major categories of under nutrition such as wasting (low weight for height) indicating acute under nutrition and stunting (low height for age) indicating chronic Under nutrition ¹⁹.

1.a] Need for study:

As UNICEF 2016 stages of world states 20 percentage of preschool children in India suffered from wasting whereas 47 and 48 percentage are underweight and stunted respectively. Illiteracy, poverty of family and variable food habits of school going children may be the contributing factors to such a finding. In Maharashtra the prevalence of under nutrition in 2012 Nagpur is 21.9 percent suffering from wasting and 22.7 suffering from underweight and in Amravati the percentage of wasting is 18.6 and underweight is 29.3 .

Among the *Karshya Nidan* most of the factors are applicable to school going children of present day due to drastic changes in diet life style of present era. As narrated by *Acharya Aparipakva dhatu Avastha of Balya* also acts as a predisposing factor for being easily prone to *Dhatu kshaya Janya Vata Vyadhi* like *Karshya*²². *Sarpipana* and *Madhur, Snigdha Basti* has been specifically indicated in *Karshya Chikitsa*²³ which has been adopted in the presence study. *Matra Basti* being variety of *Sneha Basti* has also been specifically indicated as a routine therapy in *Krisha, Durbala* and persons affected with *Vata Vyadhi*.

The selected drug of the present study *Ksheerabala Taila* is one of the *Sneha Kalpana* prepared with *Go Ksheer*, *Balamoola Kalka* and *Tila Taila which is indicated for Basti in 80* Nantmaja Vata Vyadhi. Dhatripayasyadi Ghrita described in Arogya Raksha Kalpa Druma, one of the popular Pediatric text book of *Kerala*. It is a medicated *Ghrita* processed with *Amalaki*, *Vidari*, *Ikshu swarasa and Tila Kalka* in the treatment of *Karshya*.

Minimal research studies had been carried out with *Ksheerabala Taila Matra Basti* specifically in Protein Energy Malnutrition (PEM) of children but no comparative studies have been conducted as the protocol of present study. No research studies are conducted on the efficacy of *Dhatripayasyadi Ghrita* till date.

In the present study an attempt is being taken to interpret *Karshya* by considering the *Nidana*, *Samprapti and Lakshana*a described by *Acharya* as under nutrition and not as mere PEM. Thus the present study is being selected to evaluate the comparative clinical efficacy of *Ksheerabala Taila Matra Basti* and *Dhatripayasyadi Ghrita* in *Karshya* with special reference to Undernutrition in children.

1.b]Review of Literature:

Sl. No	Literature	Reference, Chapter & verse	Information reviewed
1	Charak Samhita	Sutrasthan- Ashtoninditaadhaya- 21/15 Siddhistan- Snehavyapadsiddhi, 4/52-54	Causes Symptoms Rasa PradoshajaVyadhi Matrabasti- in vataroga and Krisha person.
2	Sushruta Samhita	Sutrasthan- Doshadhatumalakshyavr udhivigyanadhaya- 15/33	Nidan- alpabhojan Samprapti-rasadhatu fails to give nutrition to all parts of body Lakshana- body fails to function properly, production of vataroga. Chikitsa- Brimhanvasti & Ghrit prayog.
3	Ashtang Sangraha	Sutrasthan- Dividhaupakramaniyaad haya 24/53-55	Causes- <i>Langhan</i> Symptoms- prominent interpharengeal joints treatment- <i>Brimhan</i>
4	Kashyap Samhita	Khilasthan- Bhaisajyaupakramaniya adhyaya- 3/84 Sutrsthan lehaadhyaya18/12-13	Dose of Ghrita

5	Yogratnakar	Karshyadikar Page 444	Chapter- Nidan and Chikitsa
6	Bhavprakash	Madhyakhanda Karshyadhikar 40/412	Separate chapter- <i>Karshyadhika</i> r includes- <i>Nidan, Lakshan</i> , symptomatology, aetiology, pathogenesis, prognosis and treatment
7	SharangdharSa mhita	Purvakhanda chapter 7 Rogaganana	Included Karshya under the heading of Nanatmaj Vyadhi
8	Sahasrayogam	Formulation no- 124 Page 292	Ksheerabala Tailam preparation method. Indication- Nanatmaj vata vicar Agnideepana, Vata Shamana and Brimhana.
9	ArogyaRaksha Kalpadrumah	Karshya Nidan Chikitsa 28/pg.248	Treatment- Dhatripayasyadi Ghrit
10	Ayurvedic formulary of India part-1	Sneha Kalpana	Preparation of Ghrita and Taila
11	Website	Unicef.org/progressforc holdren/2006n4/undernu tritionondefination.html	Definition of Under nutrition And Prevalence of Undernutrition
12	Website	Hepatotoxity of tubers	Toxicity of <i>Vidari</i>
		of indian kudzu (pueraria tuberosa) in rats	

1.c]Review of previous research work

- 1) Clinical study of *Brimhan* effect of *Asahwagandha* with four *Anupan* on *Karshya* with respect to protein calorie malnutrition by department of Dravyaguna MUHS in 2011-12.
- 2) Study the concept of *Karshya* in *Brihatrye*e w.s.rto "*Krushamprayobhighavantirogachagrahanigata*|| cha sut. 21/14" MUHS, Nashik 2011-2012
- 3) Clinical study on the effect of *Ashwagandhadi Leha* in management of *Karshya* (underweight) children by Department of *Kaumarabhrity*a S.D.M College of Hassan in 2010.
- 4) A Comparative Clinical Study of Matra Basti in Karshya"in RGUHS Bangalore 2009.
- 5) *Vidarikandadi Vati* and *Kshirabala Taila Basti* in *karshya* of Children by department of *Kaurmarbhrity*a -IPGT&RA, Gujrat Ayurved University, Jamnagar in 2009.
- 6) Study on the effect of An Indigenous drug compound in underweight children. In R.G.U.H.S Bangalore;2005
- 7) Clinical study on underweight child and their management with Withania Somnifera in Utkal university Bhubaneswar; 2004
- 8) Clinical study on *Brimhana* effect of *Ksheera Basti* in neonates and in *Krish*a children in Jamnagar 1998

2.Aim & Objectives

2.a] Aim of the study

Comparing the efficacy of *Ksheerabala Taila Matra Basti* and oral administration of *Dhatripayasyadi Ghrita* in *Karshya*

2.b] Objectives of the study

- 1) To study the efficacy of *Ksheerabala Taila Matra Basti* on Anthropometric values and other *lakshana* of *Karshya*
- 2) To study the combined effect of *Ksheerabala Taila Matra Basti* and oral administration *Dhtripayasyadi Ghrita* on Anthropometric values and other *lakshana* of *Karshya*
- 3) To study the effect of *Ksheerabala Taila Matra Basti* and the combined effect of *Ksheerabala Taila Matra Basti* and oral administration *Dhtripayasyadi Ghrita* on Hb%, RBC, Serum Proteins and Serum creatinine

3] Materials and Methods

3.a] Source of study:

- > OPD and IPD of Kaumarabhritya.
- > Nearby schools in and around Wardha.

3.b] **Study Design:**

Randomized (Computer Generated Randomization Chart) Comparative parallel group study.

3.c] Study Type-

Interventional Study

3.d] **Sample Size**- 30

3.e]Grouping-

- 1. Group MB-will be administered with Ksheerabala Taila Matra Basti in scheduled dose
- **2.** Group MBD—will be administered with *Ksheerabala Taila Matra Basti* and *Dhatripaysyadi Ghrita* orally in scheduled dose.

Diagnostic criteria-

Presence of Clinical signs and symptoms of Karshya such as,

- 1. Shushka Udar, Greva and Nitamba (Lean/Emaciated buttocks, abdomen and neck)
- 2. Sthoola Parva (Prominent joints)
- 3. Bharaadana Asahishnuta (Inability to carry weight)
- 4. *Sira Santataha* (Prominence of vessels in the body)
- 5. Twak Asthi Shesha (Wasting of muscle tissue)
- 6. Agnisada (Poor digestion)
- 7. *Angasada* (weakness in body)
- 8. Twak Rukshata (dryness of skin)
- 9. Trishna (Thirst)
- 10. Kshutpipasa asahishnuta (Inability to withstand hunger /thirst)
- 11. Sheeta ushna asahishnuta (Inability to tolerate heat and cold)
- 12. Balakshaya/ Daurbalya (Poor physical strength)
- 13. Alpaprana (Getting tired fast on physical activities/No energy to do any work)

3.f] Inclusion Criteria-

Subjects of 3 to 10 years of age suffering from *Karshya* irrespective of sex, religion and socio economic status

3.g] Exclusion Criteria

- 1. Subjects suffering from Infectious diseases like Tuberculosis, HIV and any other systemic disorders.
- 2. Known case of Hyperthyroidism

Withdrawal criteria-

1) If the symptoms get aggravated or any secondary condition appears during study such subjects will be withdrawn from study and suitable alternative treatment will be provided free of cost till it becomes alright.

3.h] Selection of Material:

➤ The raw materials required for *Dhatripaysyadi Ghrita* and *Ksheerabala Taila* will be procured from local shop and will be verified by Department of Dravyaguna.

3.h1] Composition of Formulation

❖ Ingredients of *Dhatripayasyadi Ghrita*

SI NO	Name of the ingredient	Botanical Name	Part Used	Proportion
1	Amalaki	Emblica officinails Linn.	Fruit	1part
2	Payasya (vidarikanda)	Pueraria tuberosa DC.	Root	1part
3	Ikshu swaras	Saccharum officinarum Linn.	Stem	16 parts
4	Tila	Sesamum indicum Linn.	Seed	1part
5	Go-ghrit			4parts

❖ Ingredients of *Ksheerabala Taila*

Sl no	Name of the Ingredient	Botanical Name	Part Used	Proportion
1	Go-ksheera			4parts
2	Bala	Sida cordifolia Linn	Root	1part
3	Tila taila	Sesamum indicum Linn.	Seed	16 parts

Safety Profile-

Vidarikanda-

High dose of *Pueraria Tuberosa Methanolic Extract* (> 227.5mg/100gm BW) and continuous use for longer period even in low doses is hepatotoxic.

3.h2] **Preparation of Formulation:**

Dhatripasyadi Ghrita and Ksheerabala Taila will be prepared as per classical method in Dattatraya Rasashala as per standard protocol and will be analyzed in Pharmaceutical Laboratory.

As per Sneha Kalpana explained in Ayurvedic Formulary of India²⁵-

1part of Kalka will be taken and 16 parts of Drava will be added, then 4 parts of Sneha, will be added and boiled and stirred well continuously, when all *Dravadravya* are evaporated, the stage of paka will be tested either it is Mrudu or Madhyam. Madhyam paka will be taken for Pana. Likewise the Ksheerabala Taila will also be prepared and Mrudupaka will be taken for Basti.

3.i]Doses (Posology)

Dosage-

Ksheerabala Taila Matra Basti ²⁷–

Dose - Half Pala = 24ml for 7 days of 2 sitings with a gap of one week

Dhatripayasyadi Ghrita -

Dose -As per classical references following dosage chart is prepared and will be administered accordingly.

Age in years	Dose
3years	3.5gms
4years	4.5gms
5years	5.5gms
6years	6.5gms
7years	7.5gms
8years	8.5gms
9years	9.5gms
10years	10.5gms

3.j] <u>Duration of study</u> – 7 days of *Ksheerabala Taila Matra Basti* in 2 sitings 28 days of *Dhatripaysyadi Ghrita* Orally

Review- Every 7 days

3.k] **Follow up** –56 days with review every 14 days

3.l] Routine investigation-

Hb%, RBC.

3.m] Specific investigation-

Serum Proteins
Serum creatinine

3.n] Subjective parameters-

Lakshana of Karshya

3.0] Objective parameters-

Weight

Height

Mid arm circumference

Mid-Thigh circumference

Weight for height

BMI

Grading-

TwakRukshata

Absent	0
Mild	1
Moderate	2
Severe	3

2. Daurbalya (weakness)

Can do routine exercise/work	0
Can do rutine activity with hesitancy	1
Can do routine activity only, with difficulty	2
Cannot do routine activity too	3

<u>Agnimandya</u> (poor digestion)

Absent	0
2601	
Mild	1
Moderate	2
Severe	3

Trishna asahishnuta

Absent	0
Tolerable	1
Intolerable	2

Angasada

Absent	0
Mild	1
Severe	2

3.p] Statistical methods-The data will be analyzed by Student T test, Paired T test, Wilcoxon rank sumand the level of significance will be decided accordingly.

3.q] Assessment Of Result-

The assessment of progress will be done after 8 Weeks, that is, after completion of the course of treatment. An assessment scale shall be framed to assess the rate of improvement. At the end of the treatment, the percentage of relief will be calculated and classified under the following headings:

- 1. Maximum improvement: More than 75% improvement of the above-mentioned clinical signs and symptoms
- 2. Moderate improvement: 50 75% improvement of the above-mentioned clinical signs and symptoms
- 3. Mild Improvement: 25 50% improvement of the above- mentioned clinical signs and symptoms.
- 4. No Improvement: 0-25% improvement of the above- mentioned clinical signs and symptoms.

3.r] .PICO model:

PICO model	
Population	Subjects of the age group 3-10yrs suffering from <i>Karshya</i>
Intervention	Ksheerabala Taila Matra Basti and Dhatripayasyadi Ghrita
Comparison	Ksheerabala Taila Matra Basti with Orally Dhatripayasyadi Ghrita
Outcome	
a)Primary	Changes in lakshana of Karshya and Anthropometric measurements
b) secondary	Changes in Hb%, RBC. Serum Proteins and Serum creatinine

3.s] Intervention Table

Group	Group MB	Group MBD
Sample size	15	15
Intervention	Ksheerabala Taila Matra Basti	Ksheerabala Taila Matra Basti with oral administration of Dhatripaysyadi Ghrita
Dose	Once a day- 24ml	Once a day 24ml and Ghrita as per age
Duration	7days of 2 sittings	Matra Basti -7days of 2 sittings Ghrita – orally 28 days
Follow up period	56 days	56 days

3t]	Gnatt Chart						
		Q1	Q2	Q3	Q4	Q5	Q6
Enrolment of Patients							
Medicine preparation							
Data collection							
Writing thesis parts up to							
Meth	ods						
Data	analysis						
	Writing rest of thesis						
Submission							

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5b] Annexure -2: Budget Proposal

Mahatma Gandhi Ayurved College Hospital & Research Centre,

Salod [H], Yavatmal Road, Wardha.442004, Maharashtra.

Department

Kaumarabhritya

Title

"Comparative Study of KsheerabalaTailaMatraBastiand $DhatripayasyadiGhrita on \ Karshya$ "

5.b]Budget Proposal of Trial Medicine					
SR.No	Head	Cost perUnit(/kg)	Sample Size(kg)	Total	Justification
				cost	
1.	Amalaki	50	1 kg	50	
2.	Vidarikanda	85	1 kg	85	
3.	Tila	101	1 kg	101	
4.	Ghrita	791	12 kg	9492	
5.	Ikshu	75	48 lit	3600	
6	Bala	65	10kg	650	
7	Tila Tail	320/lit	20	6400	
8	Ksheera	40/lit	20	800	
	I	1	Total	21178	

Budget Proposal of Investigation						
SR.No	Head	Cost	per Unit	SampleSize(pt.)	Total cost	Justification
		(/patient)				
1.	CBC	-	150	30	4500	
2	LFT		220	30	6600	
				Total	11100	
Budget	Proposal of Trial Me	dicine + Bud	get Proposal o	of Investigation 2	21178+11000=	=32278

महात्मा गांधी आयुर्वेद महाविद्यालय रुग्णालय व अनुसंधान केंद्र सालोड(हि)

Name of Researcher: Trupti Thakre Guide: Dr Jyothy KB

Department: Kaumarabhritya

"Comparative Study on the effect of Ksheerabala Taila Matra Basti and Dhatripayasyadi Ghrita
in Karshya"

मुख्य संशोधकांद्वारे दिलेले प्रमाणपत्र

मी तृप्ती ठाकरे प्रमाणीत करत आहे की, मी रुग्णाच्या पालकांना उपरोक्त संशोधन अभ्यासाबद्दल तसेच संशोधनाचा उद्देश व औषधांबद्दल समाधानकारक माहिती दिलेली आहे .चिकित्सेदरम्यान कुठल्याही प्रकारची प्रतिकृल प्रतिक्रिया आढळून आल्यास ,त्याची चिकित्सा मी रुग्णाला मोफत करीन.

प्रमुख संशोधक द्वारे दिया गया प्रमाणपत्र

मै तृप्ती ठाकरे प्रमाणीत करती हू कि मैने मरीज को उपरोक्त संशोधन विषय संबंधित जानकारी तथा संशोधन का उद्देष एवं दवाई के बारे में समाधान कारक जानकारी दी है | चिकित्सा के दौरान किसी भी प्रकार का दुष्परिणाम दिखने पर मै मरीज की चिकित्सा निशुल्क कर दूंगी |

(तृप्ती ठाकरे)

मुख्य संशोधकाची नाव व स्वाक्षरी प्रमुख संशोधक का नाम एवं हस्ताक्षर

रुग्ण संमती पत्र

मी माझा पाल्य	याला स्वेच्छेने उपरोक्त संशोधन
अभ्यासामध्ये सहभागी करत आहे. मला डॉक्टरांनी संशोध	धनाचा उद्देष व औषधांबद्दल समाधानकारक माहिती
दिलेली आहे.चिकित्से दरम्यान कुठल्याही क्षणी संशोधन	अभ्यासातून मुक्त होण्याच्या हक्काची मला जाणीव आहे.

रुग्ण संमती पत्र

मै अपने पाल्य......को अपनी इच्छा से उपरोक्त संशोधन अभ्यास में सहभागी कर रहा / रही हू | मुझे चिकित्सकने उपरोक्त संशोधन विषय संबंधित जानकारी तथा संशोधन का उद्देष येवा दवाई के बारे में समाधानकारक जानकारी दी है | चिकित्सा के दौरान किसी भी समय संशोधन से मुक्त होणे के हक्क कि जाणकारी मुझे है |

साक्षीदाराची स्वाक्षरी

पालकाची स्वाक्षरी