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## 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<sup>1</sup>. The word *krusha* is derived from the root ‘*krushtanukarane*’ which means *Alpa*, *Sookshma*, *Ksheena*<sup>2</sup> (lean or emaciated). *Karshya* has been included in *Nanatmaj Vata Rog*<sup>3</sup>, *Rasapradoshaj Rog*<sup>4</sup>, *Apatarpanajanya Vyadhi*<sup>5</sup> and the person suffering from *Karshya* has been entitled as one among *Ashtonindit Purush*<sup>6</sup>. 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<sup>7</sup>. Etiology of *Karshya* has been narrated as intake of *Ruksha*, *Anna-pana*, *Langhana*, *Pramitashana*, *Vegavidharan*, *Alpabhojan* and *Ativyayam*<sup>8</sup>. Ayurveda depicts that the root cause of all the diseases is *Mandagni*<sup>9</sup>. In *Karshya* also the status of *Agni* remains *Manda*<sup>10</sup>. 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*<sup>11</sup>. The clinical presentation of *Karshya* is described as presence of *Sushka-shroni*, *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 joints<sup>12</sup>, *Sthoola parva* (prominent inter-phalangeal joints)<sup>13</sup>, inability to withstand *Pipasa* (thirst), *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*<sup>14</sup>. 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 <sup>15</sup> *Snehan* usage of <sup>16</sup> *Vrushya* and <sup>17</sup> *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 <sup>18</sup>. 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 <sup>19</sup>.

### 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 <sup>20</sup>. 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 <sup>21</sup>.

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*<sup>22</sup>. *Sarpipana* and *Madhur, Snigdha Basti* has been specifically indicated in *Karshya Chikitsa* <sup>23</sup> 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 *Krishna, Durbala* and persons affected with *Vata Vyadhi* <sup>24</sup>.

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* <sup>25</sup>. *Dhatipayasyadi Ghrita* <sup>26</sup> 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 *Dhatipayasyadi Ghrita* till date.

In the present study an attempt is being taken to interpret *Karshya* by considering the *Nidana*, *Samprapti* and *Lakshanaa* 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 *Dhatipayasyadi Ghrita* in *Karshya* with special reference to Undernutrition in children.

### 1.b]Review of Literature:

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

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

### **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 *Brihatryee* w.s.r.to “*Krushamprayobhigahavantirogachagrahanigata*|| 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 *Kaumarabhritya* 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 *Kaurmarbhritya* -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 *Krishha* 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 *Dhatripayasyadi 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 *Dhatripayasyadi 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 *Dhatripayasyadi 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***

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

##### ❖ **Ingredients of *Ksheerabala Taila***

Sl no	Name of the Ingredient	Botanical Name	Part Used	Proportion
1	<i>Go-ksheera</i>			4parts
2	<i>Bala</i>	<i>Sida cordifolia</i> Linn	Root	1part
3	<i>Tila taila</i>	<i>Sesamum indicum</i> 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 India<sup>25</sup>-

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* <sup>27</sup>–

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

*Dhatripayasyadi Ghrita* –

<sup>28</sup>  
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] Duration of study** – 7 days of *Ksheerabala Taila Matra Basti* in 2 **sittings**  
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.o] Objective parameters-**  
Weight  
Height  
Mid arm circumference  
Mid-Thigh circumference  
Weight for height  
BMI

**Grading-****TwakRukshata**

<b>Absent</b>	<b>0</b>
<b>Mild</b>	<b>1</b>
<b>Moderate</b>	<b>2</b>
<b>Severe</b>	<b>3</b>

**2. Daurbalya**(weakness)

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

**Agnimandya** ( poor digestion)

<b>Absent</b>	<b>0</b>
<b>Mild</b>	<b>1</b>
<b>Moderate</b>	<b>2</b>
<b>Severe</b>	<b>3</b>

**Trishna asahishnuta**

<b>Absent</b>	<b>0</b>
<b>Tolerable</b>	<b>1</b>
<b>Intolerable</b>	<b>2</b>

**Angasada**

<b>Absent</b>	<b>0</b>
<b>Mild</b>	<b>1</b>
<b>Severe</b>	<b>2</b>

**3.p] Statistical methods-** The data will be analyzed by Student T test, Paired T test, Wilcoxon rank sum and 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	<i>Ksheerabala Taila Matra Basti</i> and <i>Dhatipayasyadi Ghrita</i>
Comparison	<i>Ksheerabala Taila Matra Basti</i> with Orally <i>Dhatipayasyadi Ghrita</i>
Outcome	
a) Primary	Changes in <i>lakshana</i> of <i>Karshya</i> 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	<i>Ksheerabala Taila Matra Basti</i>	<i>Ksheerabala Taila Matra Basti</i> with oral administration of <i>Dhatipayasyadi Ghrita</i>
Dose	Once a day- 24ml	Once a day 24ml and <i>Ghrita</i> as per age
Duration	7days of 2 sittings	<i>Matra Basti</i> -7days of 2 sittings <i>Ghrita</i> – 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 Methods						
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 *KsheerabalaTailaMatraBasti* and  
*DhatipayasyadiGhritaon Karshya*”**

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

<b>Budget Proposal of Investigation</b>					
<b>SR.No</b>	<b>Head</b>	<b>Cost per Unit (/patient)</b>	<b>SampleSize(pt.)</b>	<b>Total cost</b>	<b>Justification</b>
1.	CBC	150	30	4500	
2	LFT	220	30	6600	
			<b>Total</b>	<b>11100</b>	
<b>Budget Proposal of Trial Medicine + Budget Proposal of Investigation</b>				<b>21178+11000=32278</b>	

## 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 प्रतिकूल प्रतिक्रिया आढळून आल्यास, त्याची चिकित्सा मी रुग्णाला मोफत करीन.

### प्रमुख संशोधक द्वारे दिला गया प्रमाणपत्र

मैं तृप्ती ठाकरे प्रमाणीत करती हूँ कि मैंने मरीज को उपरोक्त संशोधन विषय संबंधित जानकारी तथा संशोधन का उद्देश एवं दवाई के बारे में समाधान कारक जानकारी दी है। चिकित्सा के दौरान किसी भी प्रकार का दुष्परिणाम दिखने पर मैं 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 संशोधनाचा उद्देश व औषधांबद्दल समाधानकारक माहिती दिलेली आहे. चिकित्से दरम्यान कुठल्याही क्षणी संशोधन अभ्यासातून मुक्त होण्याच्या हक्काची मला जाणीव आहे.

## रुग्ण संमती पत्र

मैं अपने पाल्य.....को अपनी इच्छा से उपरोक्त संशोधन अभ्यास में सहभागी कर रहा / रही हूँ। मुझे चिकित्सकने उपरोक्त संशोधन विषय संबंधित जानकारी तथा संशोधन का उद्देश्य येवा दवाई के बारे में समाधानकारक जानकारी दी है। चिकित्सा के दौरान किसी भी समय संशोधन से मुक्त होने के हक्क कि जाणकारी मुझे है।

साक्षीदाराची स्वाक्षरी

पालकाची स्वाक्षरी