

**Generation of Empirical data in favour of Digestive theory (*Dhatwagni Siddhanta*) by comparing efficacy of *Rasa Pachak Vati* and *Punarnava Mandura* in Anemia (*Pandu roga*) through RCT**

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**Abstract:**

**Introduction:** Digestive factor (*Agni*) is a crucial factor in life. Normal functioning of Digestive factor (*Agni*) is important for longevity of life. The age (*Ayu*), colour (*Varna*), strength (*Bala*), health (*Swasth*), enthusiasm (*Utsaha*), immunity (*Oja*), energy (*Teja*) and life (*Prana*), of the human body all remain stable only when the Digestive factor is strong. The important function of *Agni* is digestion. Food consisting of six taste (*Sada rasatmaka*) consumed by us, first digested by metabolic factors located in digestive tract (*Jatharagni*) and then divided into two parts, useful part (*Anna rasa*) and waste part (*Kitta bhaga*). Vitiation (*Dusti*) of primary product of digested food (*Rasa dhatu*) and *Rasagni* is the reason for several disease. Anemia (*Pandu roga*) is a disease caused by vitiation of primary product of digested food (*Rasa pradoshaja vyadhi*), a *pitta* dominating *tridoshaja vyadhi* according to *Acharya Charak*. According to *Acharya Sushrut*, it is disease caused by vitiation of blood tissue (*Rakta pradoshaja Vyadhi*). Anemia (*Pandu roga*) is disease in which the body's lustre is diminished and the colour of skin becomes pale, which our ancient classics explain as discoloration (*Vaivarna*), dust of a *Pandanus odoratissimus* flower. **Aim:** To evaluate and compare the efficacy of

*Rasa pachak vati* and *Punarnava Mandura* in anemia (*Pandu roga*). **Methods:** 80 participants in total will be enrolled in this randomized standard controlled single blind equivalency clinical trial and split into two equal groups. Group X will receive Tab *Punarnava Mandura*, while Group Y will be administered *Rasa Pachak Vati*, for thirty days. Assessment will be conducted at baseline (day 0) and on 30<sup>th</sup> day. **Result:** Information derived from the follow-up chart and additional observations will be utilized to generate conclusions, with the outcomes being represented through diverse charts, graphs and tables. **Discussion:** Will be based on observations and results obtained.

**Keywords:** Anemia, Pallor, *Rasa pachak vati*, *Punarnava Mandura*

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**Funding** – No funding acquired from any source.

**Trial Registration** –

- IEC – MGACHRC/IEC/Sep-2023/746
- CTRI – REF/2023/12/060769 (Clinical trial registry India)

**Introduction:**

Digestive factor (*Agni*) is a crucial factor in life. Normal functioning of Digestive factor (*Agni*) is important for longevity of life. According to *Acharya Vagbhata*, all diseases arise due to the slowing down of Digestive factor (*Agni*).<sup>[1]</sup> The age (*Ayu*), colour (*Varna*), strength (*Bala*), health (*Swasth*), enthusiasm (*Utsaha*), immunity (*Oja*), energy (*Teja*) and life (*Prana*), of the human body all remain stable only when the Digestive factor (*Agni*) is strong.<sup>[2]</sup>

Digestive factor (*Agni*) is root of life and diminuation of Digestive factor (*Agni*) is life - threatening<sup>[3]</sup>. The important function of Digestive factor (*Agni*) is digestion.<sup>[4],[5]</sup> According to their locations and functions Digestive factors (*Agni*) are divided into thirteen types, which works at different levels of digestion and metabolism.<sup>[6]</sup> Though each and every Digestive factor (*Agni*) has their own importance, but among the thirteen Digestive factor (*Agni*), metabolic factors located in digestive tract (*Jatharagni*) is most important.<sup>[7]</sup> According to *Acharya Charak*, all other twelve *Agnis* are depends upon *Jatharagni*. Increase or decrease of metabolic factors located in digestive tract (*Jatharagni*) directly affects the function of metabolic factors located in tissue

(*Dhatwagni*).<sup>[8]</sup>

Food consisting of six taste (*Sada rasatmaka*) consumed by us, first digested by metabolic factors located in digestive tract (*Jatharagni*) and then divided into two parts, useful part (*Anna rasa*) and waste part (*Kitta bhaga*). *Anna rasa* then circulated and further digested by *Bhutagni* and metabolic factors located in tissue (*Dhatwagni*).<sup>[9]</sup> Metabolic factors located in tissue (*Dhatwagni*) are seven in numbers.<sup>[10]</sup>

*Anna rasa* again digested by *Rasagni* and divided into two parts useful part (*Prasad bhaga*) and waste part (*Kitta bhaga*). By useful part (*Prasad bhaga*) formation of primary product of digested food (*Rasa dhatu*) done. Same like that all *dhatu* are digested by their metabolic factors located in tissue (*Dhatwagni*) and formation of next *dhatu* (*Uttar-uttar dhatu*) occurs.<sup>[11]</sup>

*Acharya Vagbhata* has described that the extreme increase (*Vridhhi*) of metabolic factors located in tissue (*Dhatwagni*) results into decrease in *Dhatu*, while extreme decrease (*Kshaya*) of it results into increase in *Dhatu*. The extreme increase (*Ati Vridhhi*) or extreme decrease (*Ati Kshaya*) of metabolic factors located in tissue (*Dhatwagni*) which can be termed as *Dhatwagni Dusti* results into pathological increase or decrease in *Dhatu*.<sup>[12]</sup>

According to *Ayurveda*, the body is made up of three regulatory functional factors of the body (*dosha*), seven *dhatu* and three waste products (*mala*)<sup>[13]</sup>, which are accountable for being's survival. First *dhatu* is *Rasa*, the most important in all. Vitiation (*Dusti*) of *Rasa dhatu* and *Rasagni* is the reason for several disease.<sup>[14]</sup>

Anemia (*Pandu roga*) is a disease caused by vitiation of primary product of digested food (*Rasa pradoshaja vyadhi*), a *pitta* dominating *tridoshaja vyadhi* according to *Acharya Charak*.<sup>[15]</sup> According to *Acharya Sushrut*, it is disease caused by vitiation of blood tissue (*Rakta pradoshaja Vyadhi*).<sup>[16]</sup> Anemia (*Pandu roga*) is mentioned in *bruhatrayi* and *laghutrayi*. According to *Acharya Charak*, *Mandagni* is the main cause of anemia (*Pandu roga*).

Anemia (*Pandu roga*) is disease in which the body's lustre is diminished and the colour of skin becomes pale, which our ancient classics explain as discoloration (*Vaivarna*), dust of a *Pandanus odoratissimus* flower (*Ketki dhuli sannibha*). The key diagnostic sign of anemia (*Pandu roga*) is pallor (*Pandura varna*)<sup>[17]</sup>, which is a change of colour in the body. Skin pallor (*Panduta*), is caused by the vitiation of *Rakta dhatu* in the body.<sup>[18]</sup>

According to *Acharya Charak*, anemia (*Pandu roga*) is of five types, *Vataja*, *Pittaja*,

*Kaphaja, Sannipataja and Mrudabhakshanjanya.*<sup>[19]</sup> According to *Acharya Sushrut*, anemia (*Pandu roga*) is of four types, *Vataja, Pittaja, Kaphaja* and *Sannipataja.*<sup>[20]</sup>

Due to resemblance of symptoms, *Pandu roga* can be correlated with Anemia.<sup>[21]</sup> Anemia is a condition in which there is reduction in the number of RBCs per cumm of the blood and decreased concentration of Hb% in RBCs. Reduction in Hb% decreases the oxygen carrying capacity of the blood to all the tissues, resulting in paleness and other symptoms.<sup>[22]</sup> Anemia causes a weakend immune system, decreased work capacity, decreased cognitive abilities and reduced overall quality of life.

### **Need of Study:**

Till date many studies were carried out on anemia (*Pandu roga*) by using oral medications (*Shamana chikitsa*) but no study was found on various search engine like Google scholar, Shodhganga, Dhara, PubMed on the Digestive theory (*Dhatwagni Siddhanta*), to treat *Rasadhatwagni* in anemia (*Pandu roga*). Data regarding *Rasa Pachak Yoga* to treat fever (*Jwara roga*) in context to Digestive theory (*Dhatwagni Siddhanta*) is available but it is not available in the management of anemia (*Pandu roga*). It may be beneficial for the management of anemia (*Pandu roga*).

**Aim:** Generation of Empirical data in favour of Digestive theory (*Dhatwagni Siddhanta*) by comparing efficacy of *Rasa Pachak Vati* and *Punarnava Mandura* in *Pandu roga*.

### **Objectives:**

1. To evaluate efficacy of *Rasa Pachak Vati* and *Punarnava Mandura* in anemia (*Pandu roga*).
2. To compare the efficacy of *Rasa Pachak Vati* and *Punarnava Mandura* in anemia (*Pandu roga*).
3. To study and revalidate the Digestive theory (*Dhatwagni Siddhanta*) in anemia (*Pandu roga*).

### **Methods:**

### **Ethical Considerations:**

The research will begin upon approval from the Institutional Ethics Committee (IEC) of Mahatma Gandhi Ayurved College, Hospital, and Research Centre in Salod(H), Wardha, and after CTRI – REF/2023/12/060769. The committee will oversee the trial’s progress

and determine the endpoint. The researcher will be responsible for assessing any adverse effects and reporting them to the ethics committee.

The patients will be provided with written informed consent in the local language, and every aspect of the study will be explained to them before the trial's commencement. The researcher will obtain the consent of the participants.

Participant personal information will be gathered and maintained confidentially throughout the trial, including before, during, and after. Physical records will be stored securely in a protected facility accessible only to the researcher. Electronic data will be stored on a password-protected hard drive, with access restricted solely to the researcher.

### **Study Setting:**

Patients will be recruited for treatment at Mahatma Gandhi Ayurved College, Hospital, and Research Centre (MGACH&RC) in Wardha from both the Outpatient Department (OPD) and Inpatient Department (IPD) of the Department of Kayachikitsa. Additionally, patients will be selected from various peripheral camps specializing in different medical fields. A total of 80 patients will be chosen for the trial which includes a 10% dropout rate. The individuals will be divided into two groups of equal size based on the allocation ratio. Group X will serve as the control group, and Group Y will be the experimental group. The study will span 30 days for both groups, during which all measurements will be taken on days 0, 15, and 30.

### **Eligibility Criteria:**

#### **Inclusion Criteria:**

- Patients willing for written informed consent to participate in the study.
- Patient between the age group of 18 to 60 years of either gender.
- Patient having Hb% in the range of, for Male 7 to 11.9 and for Female 7 to 10.5.
- Patient having the symptoms of Anemia (*Pandu roga*) like *Agnimandya*, *Daurbalya*, *Panduta*, *Aruchi*.
- Patient of *Doshaja Pandu roga*.

**Exclusion Criteria:**

- Known case of thalessemia, sideroblastic anaemia, anaemia due to malignancies, and congenital absence of iron binding protein.
- Pregnant & lactating women.
- Known case of abnormal / dysfunctional uterine bleeding.
- Known case of CKD, CLD, CAD, and Cancer.
- Secondary anemia due to bleeding disorders.
- Patients of anemia due to intake of mud (*Mridabhakshanjanya Pandu*).

**Intervention description:**

Group X – Tab Punarnava Mandura 500mg twice a day after meal.

Group Y – Tab Rasa Pachak Vati 500mg twice a day before meal.

**Grouping and Posology:**

Detail explained in Table 01.

**Drug collection and authentication:** Reliable sources will be utilized for gathering the raw materials for the drug, and authentication and identification will be conducted through the Dravyaguna and Rasashastra department of MGACHRC, Salod(H), Wardha.

**Details of Drugs Preparation:**

*Rasa pachak Vati* will be prepared in *Dattatraya Ayurved Rasashala* Salod (H), Wardha as per standard operative procedures.

**List of ingredients of *Rasa Pachak Vati*-**

- *Holarrhena pubescens* Linn - 1 Part
- *Trichosanthes dioica* Roxb - 1 Part
- *Picrorhiza kurroa* Royle - 1 Part

**Preparation of *Rasa Pachak Vati*:** <sup>[23]</sup>

All the ingredients are collected, cleaned and crushed in *Khalva Yantra*.



Fine powder of all ingredients mix properly



All these ingredients pounded in *khalva yantra* by adding little quantity of Ghee to make a soft paste



Tablets are made and store in an airtight container after drying.

**Intervention Modification:**

Any adverse effects observed during the treatment will be documented and promptly reported to the ethics committee. Patients experiencing adverse effects will receive appropriate care and attention. In the event that participants decide to withdraw from the study, their reasons for discontinuation will be recorded and acknowledged.

**Outcome:**

- The study anticipates positive outcomes in terms of improving hemoglobin levels, resolving symptoms of anemia, and potentially validating the Digestive Theory (Dhatwagni Siddhanta) in clinical practice.
- Data from this trial could contribute to the understanding and acceptance of Ayurvedic principles in managing hematological disorders.

**Participant timeline:** Patient enrollment began in April 2024. Patients will undergo treatment for 30 days, and assessments will be conducted throughout this period, as illustrated in Figure 1.

**Sample Size:**

Formula Using Mean difference

$$n1 = n2 = 2 \frac{(Z_{\alpha} + Z_{\beta})^2 \sigma^2}{(\delta)^2}$$

$$Z_{\alpha} = 1.96$$

$$\alpha = \text{Type I error at 5\% at both sides two tailed}$$

$$Z_{\beta} = 0.84 = \text{Power at 80\%}$$

Primary Variable Effect on Haemoglobin (Hb).

Mean  $\pm$  s.d. Haemoglobin (Hb) before the treatment Punarnava Mandura =  $9.065 \pm 1.3266$

Mean  $\pm$  s.d. Haemoglobin (Hb) after the treatment Punarnava Mandura ( Control Group) =  $11.265 \pm 0.6809$

Change in Haemoglobin (Hb) 2.2

Considering 30 % superiority margin for improvement in Hb for Rasa pachak Vati group =  $2.2 * 30 = 0.66$

(Mean difference ( $\delta$ ) = 2.2

Pooled Standard Deviation = 1.00375

$$\text{Sample size } N = n1 = n2 = 2 \frac{(1.96 + 0.84)^2 (0.66)^2}{(1.00375)^2} = 36 \text{ per group}$$

Considering 10% drop out =4

Total sample size required =  $36 + 4 = 40$  per group.

### **Recruitment:**

According to the sample size calculation, a total of 40 patients will be recruited for each group, accounting for 36 participants and 4 potential dropouts. The collected data will be analyzed using suitable statistical methods. Patients with Anemia (Pandu roga) will be recruited from the outpatient and inpatient departments of Kayachikitsa at Mahatma Gandhi Ayurved College, Hospital, and Research Centre in Salod (H), Wardha, as well as from specialized peripheral camps. The study will enroll a total of 80 patients.

### **Enrolment and Intervention time schedule:**

The intervention period will span from day 0 to day 30, with follow-up assessments on day 0 and day 15.

### **Guidelines:**

This protocol complies with the SPIRIT guidelines.

### **Case Definition:**

Patients between 18 to 60 years of either sex having Hb% in the range of, for Male 7 to 11.9 and for Female 7 to 10.5 & willing to give written informed consent.



**Type of Study:**

Interventional & Conceptual Study

**Study Design:**

Randomized Standard Control Single Blind Equivalence Clinical Trial. Explained in Table No. 02

**Assessment Criteria:** Assessment will be done before and after treatment.

- **Subjective Parameters:**

1. ***Dhatwagni* assessment criteria.**

- *Jarnashakti Parikshana*<sup>[24]</sup> - Explained in Table No. 03
- Symptom of vitiation of *Rasa*<sup>[25]</sup> - Explained in Table No. 04

2. **Pandu assessment criteria**<sup>[26]</sup>.

- Gradation of Pallor (*Panduta*) - Explained in Table No. 05
- Gradation of *Agnimandya* - Explained in Table No. 06
- Gradation of Tastelessness in food (*Aruchi*) - Explained in Table No. 07
- Gradation of Weakness (*Daurbalya*) - Explained in Table No. 08

- **Objective Parameters:** CBC

**Allocation sequence generation:**

Random Sampling by Computer Generated table.

**Allocation implementation:**

The researcher or primary author will generate the allocation sequence, enroll participants, and assign them to the intervention.

**Sampling procedure:**

Randomization will be conducted using a computer-generated table to prevent bias in the study.

**Concealment of allocation:**

A third person will handle the coding to allocate subjects into groups X or Y using sequentially numbered, opaque, sealed envelopes (SNOSE scheme) to prevent bias in the study.

**Blinding:**

This study is a randomized, standard-controlled, single-blind equivalence clinical trial, meaning the participants will be blinded.

**Data collection plan:**

Data will be evaluated based on assessment criteria on day 0, day 15, and day 30 of the study.

**Study status:**

Drug preparation is in process.

**Statistics outcome:** Following the completion of the study, the data will undergo analysis using appropriate statistical tests.

**Discussion:**

The foundation of Ayurveda emphasizes the role of digestion (Agni) in maintaining health. According to Ayurvedic principles, proper digestion (especially Jatharagni) is crucial for the transformation of food into essential nutrients (Dhatu) which sustain the body's health and vitality. Anemia is described as Pandu roga in Ayurveda, characterized by pallor, weakness, and other symptoms related to vitiation of blood tissue (Rakta dhatu). Ayurvedic texts attribute anemia to Mandagni (weakened digestive fire), which affects the production of Rasa dhatu (primary product of digestion) and subsequent Dhatus. Rasa Pachak Vati aims to improve Rasa dhatu digestion and quality, thus indirectly enhancing the production of blood (Rakta dhatu). It contains herbs known for enhancing Agni and supporting digestion. If Rasa Pachak Vati or Punarnava Mandura demonstrate significant efficacy, it would promote further research and integration of Ayurvedic formulations into mainstream healthcare for anemia management. The study's findings may provide insights into personalized Ayurvedic interventions based on individual digestive capacity (Agni), supporting the idea of targeted therapies in Ayurveda. The proposed study holds promise in advancing the evidence base for Ayurvedic treatments of anemia, showcasing the relevance of ancient theories like Dhatwagni Siddhanta in modern clinical contexts.

**Conclusion:**

*Rasa pachak vati* may be as effective as *Punarnava Mandura* in the management of Anemia (*Pandu roga*) in the favour of Digestive theory (*Dhatwagni Siddhanta*).

**Dissemination:**

The protocol will be subsequently documented as a thesis to disseminate the research findings on Anemia (*Pandu roga*). The study protocol offers a comprehensive outline of the study design, methodology, data collection procedures, data analysis plan, and ethical considerations. By sharing this protocol, our aim is to contribute to the advancement of knowledge in the field and support future research endeavors through presentations, papers, and publications.

**Data availability:**

Underlying data-

This article does not include any associated data.

Reporting guidelines-

Zenodo: SPIRIT checklist for “Generation of Empirical data in favour of Digestive theory (*Dhatwagni Siddhanta*) by comparing efficacy of *Rasa Pachak Vati* and *Punarnava Mandura* in Anemia (*Pandu roga*) through RCT”

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**Acknowledgement:**

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**Competing interests:**

No competing interests were disclosed.

**Consent:**

Prior to commencing the trial, explicit consent from the patient will be obtained through both written and verbal means, utilizing the local language. The patient will receive a comprehensive explanation of all aspects of the study.

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**Tables:**

Table No. 01 – Grouping and posology.

	Group X	Group Y
Sample Size	40	40
Intervention	<i>Punarnava Mandura</i>	<i>Rasa Pachak Vati</i>
Dose and Frequency	2 <i>Vati</i> BD (250 mg each) after food	2 <i>Vati</i> BD (250 mg each) before food
<i>Anupana</i>	<i>Koushna Jal</i>	<i>Koushna Jal</i>
Route of Administration	Oral	Oral
Duration	30 Days	30 Days
Follow up	15th and 30th Day	15th and 30th Day

Table No. 02 – Showing Study Design

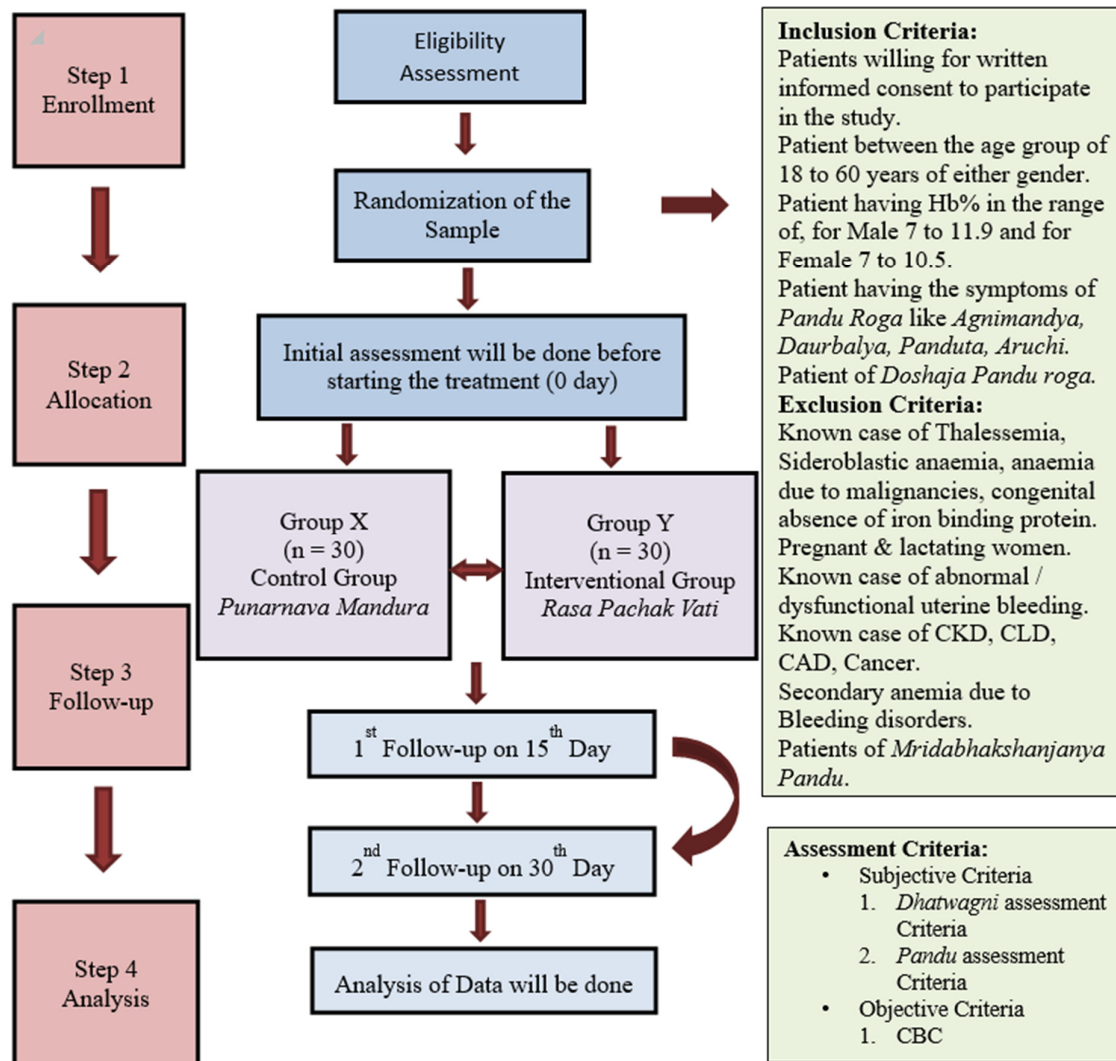


Table No. 03 – *Dhatwagni* assessment criteria

Sr.no	<i>Jarnashakti Parikshana</i>	Present	Absent
1	lightness of the body ( <i>DehaLaghavta</i> )		
2	liking towards food intake ( <i>AnnaShraddha</i> )		
3	Appetite ( <i>Kshudha</i> )		
4	exhaustiveness in the body ( <i>Klama Pariagamana</i> )		
5	timings of urination & defecation ( <i>Vegotsarga</i> )		

Table No. 04 - *Dhatwagni* assessment criteria – showing symptom of vitiation of Rasa.

Sr.No.	Symptom of vitiation of Rasa ( <i>Rasadusthti lakshana</i> )	Present	Absent
1	Excessive Salivation ( <i>Prasekam</i> )		
2	laziness ( <i>Aalasya</i> )		
3	heaviness in body ( <i>Gaurav</i> )		
4	Feeling coldness ( <i>Shita Anubhav</i> )		
5	Excessive sleep ( <i>Atinindra</i> )		
6	Excessive thirst ( <i>Trishna</i> )		
7	Shaking of body ( <i>Kampan</i> )		

Table No. 05 – Showing Gradation of Pallor (*Panduta*)

Gradation of Pallor ( <i>Panduta</i> ) – <i>Twaka, Nakha, Netravartma, Karnapali, Jiwha, Hastapadatala</i>		
Sr.No.	Symptoms	Gradation
1	Absent	0
2	Present in one site	1
3	Present in 2 – 3 site	2
4	Present in all sites	3

Table No. 06 – Showing Gradation of *Agnimandya*

<i>Agnimandya</i>		
Sr.No.	Symptoms	Gradation
1	<i>Matravaha Ahara</i> , feels comfortable, proper digestion	0
2	<i>Matravaha Ahara</i> , feels discomfort, proper digestion	1
3	Less <i>Matravaha Ahara</i> , feels more discomfort	2
4	Not able to digest even little food, feels more discomfort	3

Table No. 07 – Showing Gradation of Tastelessness in food (*Aruchi*)

Tastelessness in food ( <i>Aruchi</i> )		
Sr.No.	Symptoms	Gradation
1	Normal taste in food, feeling to eat food in time	0
2	Feeling to take food but not having taste	1
3	not feeling to take food even if hungry ( <i>Ananabhilasha</i> )	2



<b>4</b>	aversion to food ( <i>Bhaktadweshha</i> )	3
<b>5</b>	not taking food ( <i>Abhaktachanda</i> )	4

Table No. 08 – Showing Gradation of Weakness (*Daurbalya*)

<b>Weakness (<i>Daurbalya</i>)</b>		
<b>Sr.No.</b>	<b>Symptoms</b>	<b>Gradation</b>
<b>1</b>	No weakness ( <i>Daurbalya</i> )	0
<b>2</b>	Not able to perform strenuous activity	1
<b>3</b>	Cannot perform strenuous activity but can perform moderate activity	2
<b>4</b>	Not able to perform moderate activity	3
<b>5</b>	Even mild activity cannot be performed	5

**Certificate of Consent**

I have been briefed regarding the research studies for which myself in bring enrolled /or given consent to enroll I/my son/ daughter/.....I have reviewed all the information regarding the study and read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant- .....

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_

**If illiterate**

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness \_\_\_\_\_ and Thumb print of participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_

Day/month/year