Study Protocol

Comparative study on efficacy of *Murvadya Churna* with *Lauha Bhasma & Navayas Churna* in *Pandu Roga* (Iron Deficiency Anemia)

Abstract:
Pandu Roga is mainly the *Rasapradoshaj Vyadhi*which vitiates the*Pitta.*Whereas Shushruta described it as*Raktapradoshaj Vyadhi*.In *Pandu Roga* due to *Alpa Rakta Twaka*Whitish discoloration(discoloration of skin) occurs.Which can be corelated with Anemia. **Aim-**Efficacy of *Murvadya Churna* with *Lauha Bhasma* in the management of *Pandu Roga*(Iron Deficiency Anemia).
Material and Methods – Study contain 60 patients of *Pandu* will divided into two groups (each group contain 30). In Group A (Experimental group)- *MurvadyaChurna* with *Lauha Bhasma* 500mgtwo times a day after meal with warm water for 30 days& In Group B 500mg*Navayas Lauha* will administered two times a day after meal with honey. Assessment will be recorded every 15th day (15th& 30th day)**Result –** Subjective and Objectives outcomes will be assessing. **Conclusion** – *Murvadya churna* with*Lauha Bhasma* will further effectual than *Navayas Lauha.*
Key words:*Pandu Roga, Murvadya Churna, Navayas Churna, Lauha Bhasma*

Background:
According to Ayurveda, body comprises of seven *Dhatus*, which are responsible for sustenance of the being. Amongst them the first *Dhatu*i.e.,*Rasa* has given more importance. According to Charaka, *Pandu Roga* is a *Rasapradoshaja Vyadhi* which is a *Pitta* dominant *Tridoshaja* disease.[1] Whereas, Sushruta described it as *Raktapradoshaja Vyadhi*.[2,3] It is a disease in which *Vivarnata of Twaka* (discoloration of skin) is mainly *Pandu* (pallor/ yellowish-whitish) due to *Alpa Rakta* (reduced blood).[4,5] Other signs of *Pandu Roga* are *Agnimandya* (diminished appetite), *Aruchi* (tastelessness in food*), Daurbalya* (general debility), *Bhrama* (giddiness) etc.[6] The nearest correlation of *Pandu Roga* can be made with Iron deficiency Anemia, because of *Panduta* or pallor in the whole body.
Anemia itself called as deficiency of Hb% in blood & can be caused by less or few no. of RBCs as well as hemoglobin in the cells.[7] There are so many factors responsible for the iron deficiency anemia, the major common cause is deficiency of essential elements for hemoglobin synthesis (Iron, Vit. B12 and folic acid), blood loss, repeated pregnancies in female of reproductive age, worm infestation, hemolysis due to known/ unknown causes and bone marrow conditions causing suppression of red cell synthesis. Anemia is a common & serious global public health problem as well as its prevalence is in young children & women. As per the National Family Health Survey, 53.2% are of non-pregnant women and 50.4% of pregnant women of age 15-49 years were found to be anemic in 2016, whereas only 22.7% men were anemic in this age group.[8]

Ayurvedic Herbo-mineral iron preparations being devoid of hazards need to be evaluated to know their efficacy in treatment of *Pandu Roga*. Since ancient times, different these iron preparations are empirically used for treatment of *Pandu Roga*. *Murvadya Churna* is one of such ayurvedic preparations.[9] On looking at the ingredients of *Murvadya Churna*, it works by effect on *Srotasas* (micro channels) and *Agni* (digestive fire mechanism).[10] In literature, there is no studies regarding usefulness of *Murvadya Churna with Lauha Bhasma* in treatment of *Pandu Roga*. Therefore, we planned a study to analyze the effect of *Murvadya Churna* with *Lauha Bhasma*[11] in treatment of *Pandu Roga* (Iron Deficiency Anemia)

Trial plan: Randomized controlled Double arm randomized Standard controlled clinical trial. It is an Interventional study having 1:1 ratio on both parallel groups.

Methodology:

Type of trial – This is the equivalent group, double - blind, randomized, standard – controlled trial. The trial will be including, a 30 days treatment period and 15th day follow up period.

Allocation ratio – total 60 patients will be selected for the study which will be divided into two equal groups. Group A is experimental group whereas Group B is standard controlled.

Table 1. Formulations:

Sr. No.	Ingredients	Botanical Name	Part Used	Quantity
1	*Murva*	*Marsdenia tenacissima*	Stem	1 part
2	*Chitrak*	*Plumbago zeylanic*	Root bark	1 part
3	*Bala*	*Sida cardifolia*	Stem, Seed	1 part

2. *Lauha Bhasma :*

Table 2. Lauha Bhasma:-

Sr. No.	Ingredient	Botanical Name	Part Used	Quantity
1	*Lauha Bhasma*	Iron	Powder	125mg

Table 3. *Navayas Churna*

Sr.no.	Content	Botanical name	Part used	Quantity
1	*Shunthi*	*Zingiber officinale*	Rhizome	1 part
2	*Maricha*	*Piper nigrum*	Fruit	1 part
3	*Pippali*	*Piper longum*	Fruit	1 part
4	*Haritaki*	*Terminaliyachebula*	Fruit	1 part
5	*Amalaki*	*Emblicaofficinalis*	Fruit	1 part
6	*Bibhitaki*	*Terminaliyabelerica*	Fruit	1 part
7	*Musta*	*Cyperusrotundus*	Rhizome	1 part
8	*Vidanga*	*Embelia ribes*	Fruit	1 part

9	*Chitraka*	*Plumbago zeylanika*	Root bark	1 part
10	*Lohabhasma*	Iron	Powder	1 part

Study setting:

- Selection will be done from OPD (Room no.30) and IPD of Dept. of Kayachikitsa, Mahatma Gandhi Ayurvedic College & Research Centre, Salod (H), Wardha. Also, patients will be selected fromvarious specialized peripheral camps.
- **Trial Registration number** -This trial registered under CTRI with trial number**Ref. MGACHRC/IEC/August – 2020/93**
- **Diagnostic criteria:**The patients having cardinal features like*Agnimandya*(loss of apetite), *Aruchi*(tastelessness), *Panduta*(pallor), *Dourbalya*(general debility)as *Pandu Roga*
- **Eligibility criteria:** Patients between the age group 18-45 years of females.
- Patients having Hb % in the range of 7 to 11gm/dl
- Patients having the symptoms of *Pandu Roga* like *Agnimadya, Daurbalya, Aruchi, Twakavaivarnya.*

Interventions:

Group A- *Murvadya Churna* with*Lauha Bhasma 500*mg two times a day with warm water after meal

Group B – *Navayas Churna* 500mg two times a day after meal

Pathya & Apathya ahar Vihar for both groups

Pathya Ahara[12] :-

Table 4. Food grains

Food	Old wheat, rice (*Shashtik*), barley, jowar, green gram and pea
Vegetables	Patola, Palak, Dudhi, *Punarnava, Haridra, Jeevanti,* all green vegetables
Non veg	Fish, goat meat, jungle meat
Fruits	Amla, grapes, Anjeera, Chikoo, banana, mango, Kharjura, papaya, pomegranate
Milk products	Cow milk, ghee, *Navaneeta takra*
Liquids	*Gomutra, Laja Manada, Koshna Jala,Laghu Panchamula Siddha Jala*
Kshara varga	*Yavaka Kshara*
Madya varga	*Sauvira, Tushodaka*

Vihara: light exercise

Table 5. Apathya ahara[13] :

Shaka Varga	Except the above mentioned*Sahaka Varga*
Shimbi Varga	*Masha, Pinyaka*
Dal	*Tila, Sarshapa*
Tail Varga	*Bijowar tail*
Drava Varga	*Atyambupana, Madyapana*

Vihara:

Diwaswapa, Atapasewana, Ativyayama, Vegavidharana, Chinta, Shoka, Krodha

Randomization-Statistician made a block randomization the participant which fullfill the criteria which will be randomly selected for the experimental as well as controlled group with the 1:1 ratio. Treatment allocation assessment of each eligible participant will be through remote &

web based randomization. Total 60 patients will be selected for the study which will be divided into 2 groups. Group A is experiment & Group B is standard controlled group.

Blinding- Treatment which are given to both groups are blinded to all of members like participants, clinically, research assistance, drug managers, statistician &other staff members also it should be revealed until study will be completed. Throughout during the study clinician will assess all the patients are still eligible or not. Firstly, for every eligible patients' clinician should apply randomization method with the help of web- based randomization system. And that only should be given the prescription for *Murvadya Churna with Lauha Bhasma* after meal with warm water two times a day. The blinding is still kept strictly confidential during the trial unless serious adverse effects occur

Screening investigations (base line): CBC
Investigation during treatment: Hb%
Investigation (end line): CBC

Criteria for discontinuing or modifying allocated interventions: From the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises, Subject will be withdrawn and free treatment will be offered to the subject till the difficulty subsides. We will measure quantity of *Churna* for the consumption of appropriate dose for assessment and to check drug adherence, during treatment the subject will be followed up.

After treatment follow up: 15^{th} day during treatment and on 30^{th} day at the end of treatment. Patient will be advised to take normal routine diet for food intake which is advised.

Primary Outcomes: We will see the effect of Interventional drugon*Agnimandya*(diminution of Agni), *Aruchi*(tastelessness),*Panduta*(pallor in the various body parts like nails,palm, icterus*), Daurbalya*(general debility)& will see changes in values of Hb%, TIBC

Secondary Outcomes: The secondary outcome of the trial is to check for reoccurrence of the disease and to monitor adverse effects (if any) of the trial drug and to compare the effects of experimental group to that of the control group.

Relief and relapse incidents-Rrecurrence means the symptoms which are present in *Pandu Roga*like*Panduta (*pallor in various body parts), *Agnimandya (*diminution of *Agni), Daurbalya* (general debility*), Aruchi (*tastelessness). These are arising after some time after the disease got complete remission. Relief& Relapse meanFirst symptom occur after the complete subside of the symptoms of that particular disease & total time taken for complete caseation of the disease.

First relapse time is First symptom of that disease occur. Total relapse times are the addition of relapse times during both the treatment period &follow up period.

Long-term effectiveness- It means the patients who are getting much relief during first week of the treatment protocol. So, for 30 days treatment is considered as long-term effectiveness responders.

Statistical analysis: Statistically significant error is considered as 5%. Baseline characteristics, which also include analytical factors, will be presented for each member in the group. From baseline to each time point, isolated variables will be defined with frequencies and percentages,

and continuous variables will be defined with mean as well as standard deviation for data with normal distribution or median and interquartile range for the data which are not normally distributed. Wilcoxon test is applied for both experiment and control group comparison. Paired as well as Unpaired t test will be used to evaluate the data having objective criteria. The McNamara's test will be used to evaluate the data with subjective criteria.

The prognostic factors always analyze in two steps as follows: The first step is univariate analysis. The adequate relief follow-up (day 30) rates of responders will be used as dependent variables, and forecast factors, such as demographic and clinical characteristics, and the main elements of *Murvadya Churna with Lauha Bhasma*, will be used as independent variables. A regression analysis will be conducted which should be logical. The selection measures for the independent variable are defined as $\alpha = 0.1$. The next step is multivariate evaluation. Those predictive factors selected through the prior step will be always entered into two multiple regression models, taking the follow-up (day 30) adequate relief responder rates as the dependent variable.

We plan to do some sensitivity analyses. Firstly, we will compare the main and safety outcomes between all randomized patients and expose the patients. Next, we will evaluate the impact of the missing data on our primary outcome. The method of multiple attributions will be used to handle missing data. We will compare the results of primary outcome using the multiple assigned dataset and un-imputed dataset to evaluate strength.

Prearranged subgroup evaluation will be carried out in relation to the primary outcome—adequate relief. The key analysis for every subgroup will be an unadjusted assessment of interaction in a logistic model.

Statistical analysis: Data having Normal Distribution will be done by paired & unpaired t test

Data having non normal distribution will be done by Wilcoxon signed rank test & Mann Whitney u test

Total follow up: At 0-day, 15^{th} day & 30^{th} day the patient will be followed up
Follow up Period: At $15^{th\ day}$ during the treatment and at 30^{th} day on the completion of the treatment
Enrolment and interventions time schedule: Drug will be given from 0 to 30 days and after that follow up on 15^{th}& 30^{th} day.
Recruitment: By computerized simple random sampling method 60 patient will be recruited (30 in each group)

Implementation: Principal Investigator will enroll and allocate the patient.

Methods: Data collection, analysis and management
Data collection method: Assessment criteria
Subjective -*Panduta (*pallor), *Aruchi*(tastelessness), *Agnimandya*(anorexia), *Daurbalya (*generalised weakness)
Objectives -CBC, KFT(before and after treatment)
The assessment will be done according to the gradations on 0^{th}, 15^{th} (during treatment), on 30^{th} day (at the end of treatment)

We will stay in touch of the patients by taking contact no. & timely advice them for medication & follow up and data of follow up patient will be stored in documentation with reason.

Gradation of Symptoms with validation: -Symptoms will see before, during and after treatment using gradation of symptoms for clinical research methodology

Table 6. **Gradation of Symptoms with validation**

Duration	Symptoms
0, 15th & 30th days	*Panduta* *Agnimandya* *Aruchi* *Daurbalya*

Duration	Investigation
0,15th& 30th day	• Hb% • MCV • MCH • MCHC • KFT

i. *Panduta* (pallor) : In *Twaka, Nakha, Netravarnata, Karnapali, Jiwha, Hastapadatala*

Sr.no.	Symptoms	Gradation
1	Absent	0
2	Present in one site	1
3	Present in 2-3 sites	2
4	Present in all sites	3

ii. *Agnimandya* (Diminution of *Agni*): -

Sr.no.	Symptoms	Gradation
1.	*Matravaha Ahara*, feels comfortable proper digestion	0
2.	*Matravaha Ahara*,discomfort, proper digestion	1

3.	Less than *Matravaha Ahara*, feels more discomfort	2
4.	Not able to digest even little food feels more discomfort	3

iii. *Aruchi* (Tastelessness in Food) :-

Sr.no.	Symptoms	Gradation
1.	Normal taste in food, feeling to eat food in time	0
2.	*Aruchi*- feeling to take food but not having taste	1
3.	*Ananabhilasha*- not feeling to take food even if hungry	2
4.	*Bhaktadwesha*- aversion to food	3
5.	*Abhaktachchanda*	4

iv. *Daurbalya* (General debility): -

Sr.no.	Symptoms	Gradation
1.	No *Daurbalya*	0
2.	Not able to perform strenuous activity	1
3.	Not able to perform moderate activity	2
4.	Cannot perform moderate activity but can perform moderate activity without any difficulty	3
5.	Even mild activities cannotbeperformed	4

Plan to promote participants retention and complete follow up: We will stay in touch with patient by taking contact no. and timely advise them for medication and follow up and data of follow up will be stored in documentation with reason.

Data management: The data will be collected from patients by doing clinical evaluation after taking written consent form from the patient. Data will be collected using planned questionnaire filled during interview of the patient. Data will be entered in master sheet and analysed by using suitable statistical technique and data coding will be done by principal investigator.
Outcome will be compared using paired and unpaired student 't' test.
Ethical consideration: Approval from research ethics committee has taken - Ref. No. MGACHRC/ IEC/August- 2020/ 93. After the ethical approval from IEC study will be started.
Consent or assent: The written consent will be taken before starting the study from the patient.
During the study, privacy should be maintained of each &every patient.
Dissemination policy: The data will be circulated by paper publication.
Any intended use and authorship eligibility guidelines of professional writers

Informed consent materials: Model consent form and other associated documentation with all information will be given to participant.

Expected Result:

Expected outcome result in control group with intervention *Murvadya Churna with Laha Bhasmais* effective in subsiding the symptom of *Panduta*(pallor), *Aruchi (*tastelessness), *Agnimandya*(diminution of *Agni), Daurbalya*(general debility)aswell as it is effective in increasing Hb%level. By following *Pathya* and *Apathya* , during treatment patient who will take all follow up will have a reduced amount of chance of recurrence of symptoms as compared with standard *Navayas Churna.*

Discussion:

This study will be conducted with the aim to compare clinical efficacy of *Murvadya Churna* with *Llauha Bhasma*& *Navayas Churna* in *Pandu Roga* (Iron deficiency anaemia). According to ayurvedic literature *Deepana, Pachana, Krumighna, Raktavardhaka* treatment is given to cure the *Pandu Roga.* We will observe that both *Murvadya Churna* with *Lauha Bhasma* & *Navayas Churna* will effectively reduce signs & symptoms of *Pandu Roga* (Iron deficiency anaemia) with reference to Hb%, MCH, MCHC, MCV. *Murvadya Churna*with *Lauha Bhasma*contains *Murva (Marsdenia tenacissima), Chitraka (Plumbago zeylanica), Bala (Sida cordifolia)* with *Lauha Bhasma.*In these *Murva* is having *Raktashodhaka &Krimighna* properties, while *Chitraka* having *Deepana, Pachana* properties. *Bala* is*Sheeta* in*Veerya* &*Madhura Rasa* which is effective in *Pittaja Vikaras. Lauha Bhasma* is also an important component which is the iron preparation it is having the haematitic activity & Haemoglobin regeneration efficacy. *Navayas Churna* is having the contents like *Triplala (Haritaki, Amalaki, Bibhitaki), Trikatu (Shunthi, Maricha, Pippali), Vidanga (Embelia ribes), Musta (Cyperus rotundus), Chitraka (Plumbago zeylanica), Lauha bhasma* (Iron). These all ingredients having the properties like *Deepana, Pacahana, Raktavardhaka & Balya[14],* which are helpful in *Samprapti Vighatana* (breaking the pathogenesis) so helpful in reducing the symptoms of *Pandu Roga.* But in this study, we analyse the comparison in between both the formulations & effects on subjective as well as objective parameters. Total effects will show which formulation is highly effective in *Pandu Roga.*

Khatib et.al. reported about health economic modelling of childhood anaemia interventions in developing countries[15]. A number of studies related to anemia among women and during pregnancy were reported[16-20]. Mithra et.al. reported on interventions for addressing anemia among children and adolescents [21]. Shrivastava et.al. reported about effectiveness of intravenous iron sucrose in management of iron-deficient anemia of pregnancy[22]. Some key studies about anemia were reviewed[23-25].

Conclusion*:*

From the above supposed to conclude is the interventional drug *Murvadya Churna with Lauha Bhasma* is 10% further more effective in *Pandu Roga* patient as compared to *Navayas Churna* with minimum side effects.

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