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A Clinical Study to Evaluate the Efficacy of Gudanagaradi Gutika in Pandu Roga with Special Reference to Iron Deficiency Anemia - A Study Protocol

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I. INTRODUCTION

Our ancient Classics explain Pandu Roga, a sickness where the skin's colour fades and the body loses luster, as "Vaivarnaketekidhulisannibha." The primary diagnostic characteristic of Pandu Roga is the body's color change, or panduvarna(1) (pallor). Pallor, the primary feature of Pandu Roga, can be associated with anemia, which is caused by a reduction in the total amount of red blood cells in circulation and a drop in hemoglobin when compared to normal for that age and gender. The two primary factors that are crucial to the creation of Rakta are Ranjaka Pitta and Rakta Dhatwagni. Regarding its role in coloring rasa and participating in Rakototpatti, Ranjaka Pitta is one of the kinds of pitta that is primarily found in the stomach, liver, and spleen.

According to WHO estimates, around 2 billion people worldwide suffer from anemia, with iron deficiency accounting for about 50% of cases. The frequency of anemia in women between the ages of 15 and 49 is 29.9% worldwide. The prevalence is 36.5% in pregnant women and 29.6% in women of reproductive age who are not pregnant. According to WHO estimates, 40% of pregnant women globally and 42% of children under the age of five are anemic. The prevalence of anemia among children aged 6-59 months is 39.8%. (3) In order to provide a safe and effective treatment, more research is therefore required. 40 patients will get Gudanagaradi Gutika 500 mg BD for thirty days as part of this study. The rooksha, ushna, deepan, and pachan qualities of Gudanagaradi Gutika are beneficial in the production of aampachana and strotovishodhana. Because mandoor bhasma is erythropoietic, it helps in treat iron deficiency anemia by raising hemoglobin levels. This medication was selected for this study. (9)

II. REVIEW OF LITERATURE

All of the traditional Ayurvedic texts, such as Brih-trayi, Laghu-trayi, and Nighantu, in addition to more current textbooks, will be studied. We'll search a variety of websites, including PubMed, Google Scholar, Scopes, Articles, Journals, and Research Papers, for relevant content.

III. MODERN LITERATURE

The prevalence of iron deficiency anemia is high in both urban and rural populations. Iron deficiency anemia (IDA) is frequently caused by a diet low in iron, RBC breakdown, RBC production deficiency, and increased blood loss. (5) Pale skin, weakness, exhaustion, shortness of breath, and other symptoms are among the clinical signs of iron deficiency anemia (IDA). (6) The diagnosis is also predicated on the iron status, bone marrow morphology, and peripheral blood results. Parenteral and oral iron therapy are the mainstays of treatment for iron deficiency anemia. (7)

IV. AYURVEDIC LITERATURE

Acharya Charaka states that the pitta becomes inflamed and enters the Hridaya as a result of the etiological conditions. This inflamed pitta vitiates the Hridaya avasthit sadhaka pitta, which is then caused by vayu to emerge via the dasadhamani and disperse throughout the body. It also acquires sthana sanchaya in between the mansa and twacha, resulting in pandu, haridra, harita varuna, and other manifestations, ultimately leading to Pandu Roga. The body's bala, varna, sneha, and oja are decreased as a result of the Pitta-predominant vata and other doshas vitiating the rakta and other dhatus. As a result, dhatus characteristics diminish, leading to Raktalpata Medalpata, Ojakshrinata, Indriya Saithilya, Nishaar, and Vaivarna, collectively referred to as Pandu Roga. (4)

Drug Review[8,9] –

गुडनागरमण्डूरतिलांशान्मानतः समान्|

पिप्पली द्विगुणां कुर्याद्गुटिकां पाण्डुरोगिणे||७२||

This yoga is mentioned in Charak Samhita Chikitsa Sthana 16th chapter, Pandu Roga Chikitsa Adhyaya verse 72 and content of its contents are explained [Table 2]

Method of Prepration of Yoga – This yoga is made as described in the Charaka Samhita in the form of Gutika and is taken with lukewarm water.

V. NEED OF STUDY

1) Many forms of iron elements are frequently recommended in modern medicine to treat individuals with iron deficiency anemia, yet these treatments have notable side effects. Constipation, tooth discoloration, nausea, vomiting, epigastric pain, metallic taste, and other symptoms are some of the frequent side effects of oral iron consumption. Thus, as the Ayurvedic Classics make clear, finding a better option requires seeking out safe and effective Ayurvedic treatment. As a result, the goal of the current study is to deliver a medication that is least expensive, safe, and effective.
2) Many clinical trials have been carried out on Pandu Roga; nonetheless, there is still a study void regarding Gudanagaradi Gutika's therapeutic efficacy.
3) To standardize the least expensive and most effective Ayurvedic management approach, based on the rules of Agni, Tridosha, and Panchbhotik, to dissolve the Etiopathogenesis of Pandu Roga.

VI. SOURCE OF DATA

This clinical study will be carried out on patients thus patients form the material for this study. Total of 40 patients of either sex of age group 25-45 years will be selected randomly from OPD and IPD of Shree Krishna Government Ayurvedic College and Hospital, Kurukshetra, Haryana.

VII. AIMS AND OBJECTIVE

- To study the effect of drug on clinical parameters and biochemical findings associated with Pandu Roga (Anemia).
- To provide cheap, safe, and effective treatment from ayurveda to Pandu Roga patients.
- To rule out secondary causes that count for Iron Deficiency Anemia and to prevent complications of anemia.
- To standardize an ayurvedic line of treatment both drug and dose which may have an effective role in the management of patients of Pandu Roga.
- To explain Pandu Roga based on a critical review of classical text of ayurveda and with the help of modern literature.
- To advise preventive measures to check the occurrence of disease in individuals and masses.

1) *Case Definition* - A special proforma that incorporates all of the Ayurvedic elements of a thorough history and physical examination together with contemporary guidelines will be created. This proforma, which has a thorough history, signs and symptoms, and other information, will be used to evaluate each patient. Every patient's vital indicators, including blood pressure, heart rate, respiration rate, and temperature, will be carefully monitored. Before and following the study, laboratory studies will also be conducted. Before the trial begins, all patients who were selected for it will be made aware of its purpose and their consent will be sought.
2) *Type Of Study:* Single centered, Simple Random Sampling, Open Label Clinical Trial.
3) *Research Question* - Is the Efficacy of Gudanagaradi Gutika in Pandu Roga (Iron Deficiency Anemia)?

VIII. HYPOTHESIS

1) NULL HYPOTHESIS (H0):- There is no significant efficacy of Gudanagaradi Gutika in the management of Pandu Roga (Iron Deficiency Anemia).
2) ALTERNATE HYPOTHESIS (H1):- Gudanagaradi Gutika is significantly effective in the management of Pandu Roga (Iron Deficiency Anemia).
3) Site of Study - Shri Krishna Govt. Ayurvedic College and Hospital, Kurukshetra, Haryana.
4) Posology - 1 gutika of Gudanagaradi Gutika BD (Each of 500 mg twice a day with lukewarm water)

A. Inclusion Criteria –

1) Patients fulfilling the diagnostic criteria for Pandu Roga.
2) All patients of the age group (25-45 years) irrespective of any sex, community, and locality will be included.
3) The patient is willing to sign the consent form.
4) Iron Deficiency Anemia (IDA) of mild & moderate types (Hb% within the range of 8-11gm/dl) will be included.[Table:2]

B. Exclusion Criteria –

1) Patients not willing for clinical trials.
2) Patient below age 25 and above age 45 years.
3) Dimorphic Anemia will be excluded.
4) Anemia other than IDA will be excluded.
5) Patients with acute blood loss will be excluded.
6) Anemia due to Leukemia & other malignant disorders will be excluded.
7) Patients with a history of other systemic diseases such as hypertension, Diabetes mellitus, renal failure, CVD, etc.
8) Hb% below the range of 8gm/dl.
9) Pregnant and lactating women.

C. Discontinuation Criteria –

1) Any other acute illness
2) Blood hemoglobin level becomes less than 5 gm/dl during treatment.
3) Any severe untoward effect.
4) Patients not willing to continue.

Follow-Up – Throughout treatment, patients will be seen every tenth day to monitor any changes in symptomatology and to determine any complications.

IX. DISCUSSION

Pandu Roga is a disorder characterized by a reduction in body luster and a fading of skin color, primarily due to an exacerbated pitta. This inflamed pitta vitiates the Hridaya avasthit sadhaka pitta, which is then caused by vayu to emerge via the dasadhamani and disperse throughout the body. It also acquires sthana sanchaya in between the mansa and twacha, resulting in pandu, haridra, harita varuna, and other manifestations, ultimately leading to Pandu Roga. The body's bala, varna, sneha, and oja are decreased as a result of the Pitta-predominant vata and other doshas vitiating the rakta and other dhatus. It is comparable to anemia, namely iron deficiency anemia. The rooksha, ushna, deepan, and pachan qualities of Gudanagaradi Gutika are beneficial in the production of aampachana and strotovishodhana. As a result, it aids in balancing doshas and Mandoor Bhasma, which helps treat iron deficiency anemia by raising hemoglobin levels due to its erythropoietic nature. Therefore, it might be really helpful for Pandu sufferers, or as we might say, for individuals with iron deficient anemia.

A. Subjective Criteria

All the Symptoms will be assessed by using the Symptom Rating Scale and these symptoms are-

1) Vaivarnyata (Pallor or paleness)
2) Aruchi/ Annadvesha (Anorexia)
3) Daurbalyata (Weakness)
4) Shrama (Fatigueness)
5) Shwasa (Dyspnoea)
6) Hridayaspanda (Palpitation)
7) Shotha (oedema)
8) Bhrama (Giddiness)
9) Atinidra (Excessive sleep)
10) Gatrashula (Body ache)

B. Objective Parameters

Following investigations will be done for safety and efficacy of the drugs and to exclude the cases as per the exclusion criteria mentioned earlier.

1) Blood for total RBCs, WBC count, DLC, Hb gm%, ESR, PCV, MCV, MCH , MCHC.
2) Serum ferritin level, Serum iron level, Total iron binding capacity (TIBC).
3) Peripheral blood smear (PBS)
4) Stool routine and microscopic examination.
5) Urine routine and microscopic examination.
6) FBS, Lipid Profile, LFT & RFT.

X. CRITERIA FOR THE ASSESSMENT OF OVERALL EFFECT OF THE THERAPIES

Clinical parameters measured both before and after the completion of the task will be used to evaluate the outcomes, and additional findings will be assessed using the tabular form. [Table 3].

XI. STATISTICAL ANALYSIS

Based on the aforementioned observations, data will be collected and statistically analyzed using the mean (x), standard deviation (S.D.), and standard error (S.E.). The relevant statistical test that is required will be used. The results acquired will be explained as follows:

• Insignificant - P < 0.10
• Significant - P < 0.05,
• Highly Significant - <0.01 • Highly Significant - P >< 0.001

XII. SUMMARY AND CONCLUSION

After the aforementioned study, the work will be compiled and the outcome will be determined with the use of statistical data.

XIII. ETHICAL CONSIDERATION

The ethical committee has approved the research topic following a thorough review and presentation.

XIV. ASSENT OR CONSENT

In-depth treatment information will be provided to subjects in their mother tongue. Patients will be requested to obtain written consent before the experiment starting.

XV. RESULTS

After being tallied and statistically assessed using relevant tests and the appropriate level of significance, the treatment's outcomes will be reported.

Table 1 : Contents of drug -

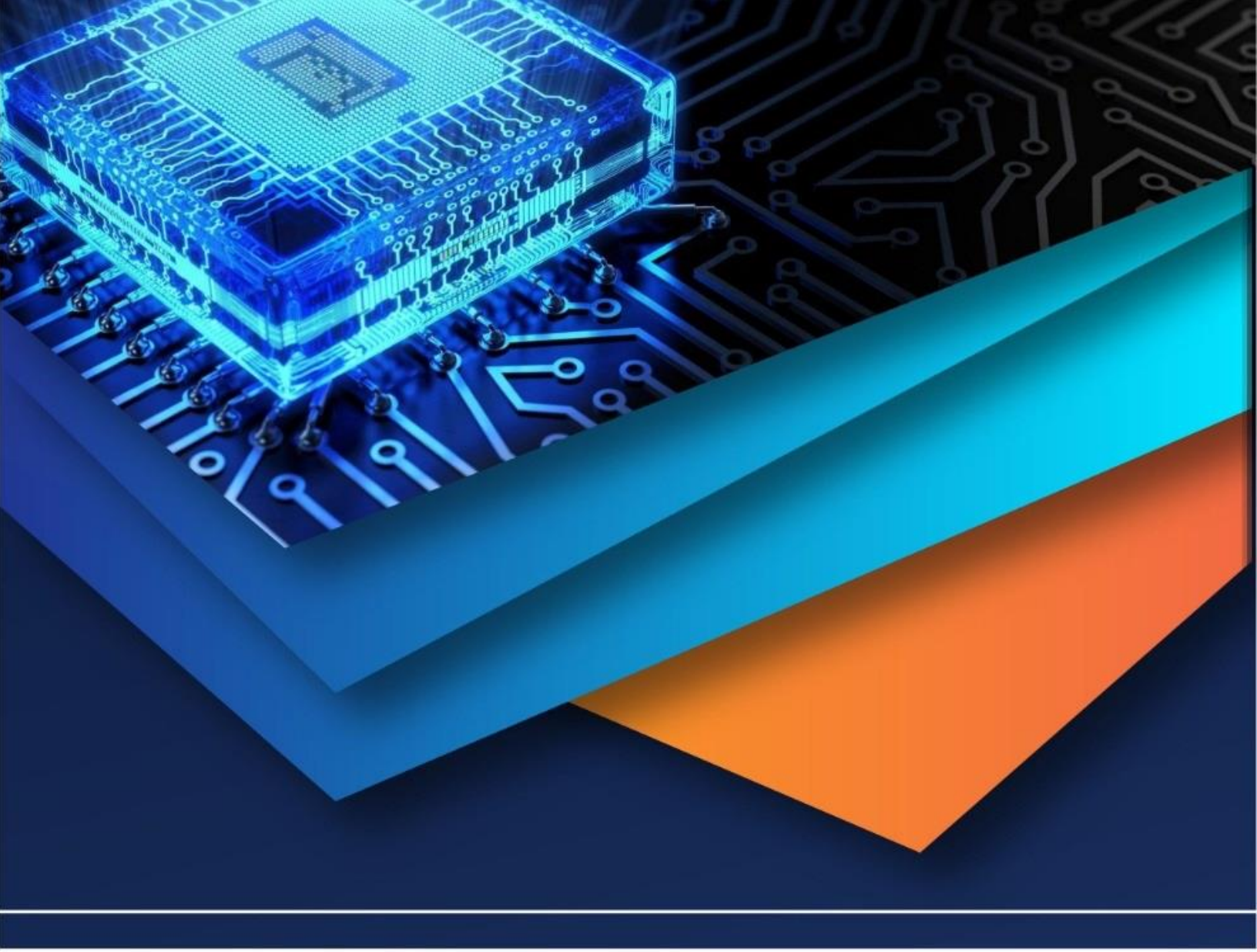
Dravya	Botanical Name	Part used	Quantity
Puran Guda	Jaggery	Guda	1 part
Mandoor Bhasma	Ferric oxide	Bhasma	1 part
Sauntha	Zingiber officinale	Rhizome	1 part
Tila	Sesanum indicum	Seed	1 part
Pippali	Piper longum	Fruit	2 part

Table 2: Grading of Blood Hemoglobin Level

Grading	Male	Female
Go- Normal	Hb>=13	Hb >=12
G1- Mild Anaemia	Hb=11-12.9	Hb=11-11.9
G2-Moderate Anaemia	Hb=8-10.9	Hb=8-10.9
G3-Severe Anaemia	Hb<8	Hb<8

Table 3 : Result and assessment -

S. No.	Positive Result Findings	Assessment
1.	Less than 25%	Non-satisfactory
2.	25% to 50%	Good
3.	50% to 75%	Satisfactory
4.	75% to 100%	Excellent



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