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Comparative Effectiveness of *Panchamrut Parpati* and Placebo in Management of *Grahani* W.S.R. to Irritable Bowel Syndrome - Study Protocol for a Single Blind, Randomized Controlled Trial

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Abstract: Background: Ayurveda has described several treatment modalities regarding the treatment of Grahani Roga including the usage of herbs and formulations, yoga and lifestyle modifications. On the other hand, systematic data regarding their efficacy relative to placebo are not currently available. The purpose of this study is to compare the efficacy of the Ayurvedic formulation Panchamrut Parpati with a placebo, which contains an inert component called starch, in the treatment of Grahani Roga patients.

Methods and design: In a prospective, single- centered, randomized controlled trial,60 patients, between 19 and 60 years, diagnosed with Grahani Roga, presenting with cardinal features of Grahani Roga as presented in Ayurvedic texts, two groups will be randomly assigned. In Group one, the patients will receive Panchamrut Parpati and in Group two, patients will receive Placebo filled with starch. Guidelines regarding Pathya-apathya will be given to both the groups. The course of treatment will last for 28 days for both groups. Outcomes will be evaluated on 14th&28th (During treatment) & 56th day (post-treatment).

Result:The primary result will be assessed by checking the grading of the cardinal symptoms of Grahani Roga mentioned in Ayurvedic texts. Secondary outcome will check for improvement in laboratory investigations and quality of life of the patient.

Conclusion: This trial compares the efficacy of Panchamrut Parpati with Placebo in the patients of Grahani roga. Panchamrut Parpati is envisioned to improve the symptoms of Grahani Roga, thus proving to be effective in management of patients of Grahani Roga.

Trial registration: CTRI/2023/07/055048.

Keywords: Grahaniroga, Randomized trial, Panchamrut parpati, Placebo, controlled trial.

I. BACKGROUND

In the present era, *Grahani Roga* is the prime disorder of the gastrointestinal tract because of its direct relation to improper dietary habits along with a sedentary and stressful lifestyle. In Ayurveda, *Acharya Sushruta* stated that *Grahani* is situated between *Amashya* & *Pakwashya*, and is known as the 6th *Kala* i.e.*Pittadhara Kala*.[1]*Acharya Charaka* considers *Grahani* as a site of *Agni* (digestive enzymes) and normally it restrains the downward movement of undigested food and after digestion, it releases the food through the sides of its lumen. In abnormal conditions, it gets vitiated due to *Agnimandhya* and releases the food in undigested form only.[2]*Grahaniroga* manifests signs & symptoms like *Muhurbadham Muhurdravyam mala pravriti* (person voids stool in large quantity either in solid or liquid form)[3], *Trishna* (morbid thirst). *Arochaka* (anorexia), *Vairasya* (distaste in mouth), *Praseka* (excessive salivation) and *Tamaka.* The patient also suffers from *Shunapadakara* (edema in legs and hands), *Asthiparvaruka* (pain in bones and joints), Vomiting, Fever, Eructations having a metallic smell, the smell of *ama* and bitter along with sour tastes[4]. Based on all signs and symptoms *Grahani roga* is correlated with Irritable Bowel Syndrome. IBS is a gastrointestinal disorder characterized by altered bowel habits and abdominal pain in the absence of detectable structural abnormality. No clear diagnostic markers exist for IBS, all definitions of the disease are based on clinical presentation. In IBS biopsychosocial factors are also thought to play an important role along with luminal factors such as diet and gut microbiota.[5]

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IBS affects around 11% of the population globally[6]. It most commonly occurs in young people, presenting before the age of 45 years. However, some reports suggest that the elderly are troubled by IBS symptoms up to 92 % as often as a middle-aged person. Young women are affected 2-3 times more often than men[7].

II. METHODS

A. Patients

1) *Patients fulfilling the following criteria shall be included:* Patients of either gender with the age group of 19-60 years presented with cardinal features of *GrahaniRoga* as described inAyurvedic texts, Randomly selected, who arewilling and able to participate in the study and provide written informed consent.
2) *Patients are excluded for the following criteria:* The patients below 19 years and above 60 years of age; who are suffering from Gastritis, intestinal obstructions, intestinal tuberculosis, ulcerative colitis, and other abdominal disorders; who are suffering from major systemic illnesses necessitating long-term drug treatment like Hyperthyroidism, Inflammatory bowel disease, Tuberculosis, Uncontrolled Diabetes, Hypertension, Psycho neuro-endocrinal disorders; Patients with concurrent serious hepatic/renal disorders, severe pulmonary dysfunction, or any type of malignancies; Patient on prolonged (>6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc.; Alcoholics and any other drug abusers; Pregnant and lactating women and The patient who has a history of Hypersensitivity to the trial drug or any of its ingredients.

The research has received approval from the Institutional Ethics committee vide no. SKAU/ Acad/2022/6758) and is carried out in compliance with the standard operating procedures for clinical trials (Declaration of Helsinki). The registration number for the trial is CTRI/2023/07/055048. Every patient gives their informed permission. The trial is currently in the hiring stage. The medication was purchased from a reputable pharmaceutical company that supplied quality control reports for two different medications.

B. Randomization

Patients are assigned at random to Groups A and B in a 1:1 ratio through a computer generated randomization sequence.

1) *Study design:*

Every patient participating in this prospective, single blinded, randomized controlled trial is given an Ayurvedic diagnosis prior to randomization.

Following randomization, patients in Group A, each Patient will be advised for taking *Panchamrita Parpati* (Capsule form) in the dose of 250 mg with Normal water twice daily for 28 days. Patients in Group B will be advised to take a Placebo (1 capsule) with normal water twice daily for 28 days. Contents of *Panchamruta Parpati* are listed below:

Table no: 1 - Contents of *Panchamruta Parpati*

Sr.No.	Drug Name	Botanical Name	Quantity	Part used
1.	*Sudha Parad*	Purified Mercury	48gm	Purified
2.	*Sudha Gandhak*	Purified Sulphur	96gm	Purified
3.	*Loha Bhasma*	Incinerated Iron	24gm	*Bhasma*
4.	*Abhraka Bhasma*	Incinerated Mica	12gm	*Bhasma*
5.	*Tamra Bhasma*	Incinerated Copper	6gm	*Bhasma*

Figure 1: Trial Design

2) *Outcomes:*

The principal result will be assessed by checking the grading of the cardinal symptoms of *GrahaniRoga* mentioned in Ayurvedic texts. Secondary outcome will check for improvement in lab investigations and quality of life of the patient. Results will be assessed on 14th& 28th (During treatment) & 56th day (post-treatment). The improvement in *Grahani Roga's* signs & symptoms mentioned in Ayurvedic texts will be used to evaluate the outcome. To establish the results statistically each sign & symptom will be given a specific score.

Table no 2: Assessment Criteria

Sr.no.	Symptoms	Grading

1.	*Muhubaddha/Muhudrava Mal pravriti (*Alternate loose motion with constipation)	
	Passing of normal consistency stool (1 time/day).	0
	Passing stool (1-2 times /day) irregular, without pain.	1
	Passing stool (2-3 times /day) irregular, without pain.	2
	Passing stool (3-4 times/day) just after meals, irregular, with pain.	3
	Passing stool (4-6 times/day) just after meals, irregular, with pain.	4
	Passing stool more than 6 times/day just after meals, irregular, with pain.	5
2.	Trit /Trishna (Thirst)	
	No Trit.	0
	Occasional Trit.	1
	Very often Trit.	2
	Always Trit.	3
3.	*Aruchi (*Tastelessness)	
	Willing towards all Bhojya Padarth.	0
	Unwilling towards some specific Aahara but less than normal.	1
	Unwilling towards some specific Rasa i.e. Katu/ Amla/ Madhura food.	2
	Unwilling for food but could take the meal.	3
	Unwilling toward unliking foods but not to the other	4
	Totally unwilling for the meal.	5
4.	*Aalasya* (Laziness/ Absence of Enthusiasm)	
	No Alasya (Doing satisfactory work with proper vigor and on time).	0
	Doing satisfactory work / Late initiation, like to stand in comparison to walk.	1
	Doing unsatisfactory work / Late initiation, Like to sit in comparison to stand.	2
	Doing little work, very slow, like to lie down in comparison to sitting.	3
	Don't want to do work / No initiation, Like to sleep in comparison to lie down.	4
5.	*Vidaha (*Heartburn)	
	Normal, No vidaha.	0
	Occasionally after taking spicy food.	1
	Once in the week after taking spicy food.	2

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	Every day after taking spicy food.	3
	Burning all the time even after normal food.	4
6.	Chhardi (Vomiting):	
	No vomiting at all.	0
	Frequency of salivation every day (Asyapraseka).	1
	Feels a sense of nausea and vomits occasionally.	2
	The frequency of vomiting is 2-3 times or more per week and comes whenever daha/ pain is aggravated.	3
	The frequency of vomiting is daily	4
	Frequency of vomiting after every meal or even without meals.	5
7.	*Praseka* (Excessive Salivation)	
	No Praseka at all.	0
	Frequency of salivation occasionally.	1
	Frequency of salivation 2-3 times/wk.	2
	Frequency of salivation every day.	3
	Feels a sense of nausea and vomits occasionally.	4
8.	Amlodgara (Acid Eructation)	
	No Amlodgara at all.	0
	Occasionally during the day/night for less than half an hour after meals.	1
	Amlodgara occurs daily 2-3 times for half to one hour and is relieved by sweets, water, and antacids.	2
	Amlodgara occurs daily 2-3 times for half to one hour and is relieved by digestion of food or vomiting.	3
	Amlodgara for greater than 1 hour not relieved by any measure.	4
	Amlodgara disturbs the patients, even small amount of fluid regurgitates to the patient's mouth.	5
9.	*Jwara* (Fever)	
	No Fever.	0
	Occasional Fever Subsides by Itself.	1
	Occasional Fever subsides by Drugs.	2
	Remittent Fever	3
	Continuous Fever.	4
10.	*Shoonpaadkaraha* (Swelling in Legs & Hands)	
	Normal, No Swelling.	0
	Occasional Swelling around ankle joint.	1
	Occasional Swelling in legs and hands.	2

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	Continuous Swelling in legs and hands.	3
11.	*Asthiparvaruk*(Pain in Bone & Joints)	
	No pain	0
	Mild pain in bone and Joints	1
	Moderate pain in bone and joints but no medication required.	2
	Excessive pain in bone and joints, medication required.	3
12.	*Kasa* (Cough)	
	Absent.	0
	A few times do not need medication.	1
	Frequent coughing can be controlled by medication.	2
	Very Frequent coughing not even controlled by medication	3
13.	*Klama* (Fatigue without Physical Exertion)	
	No klama	0
	Occasionally feeling of lassitude without Sharma remains for some time and vanishes.	1
	Lassitude without Sharma daily for some time.	2
	Lassitude without Sharma daily for a long duration.	3
	Always feels tired and has no enthusiasm	4
14.	*Karnakshweda* (Tinnitus)	
	Absent.	0
	Occasional and tolerable.	1
	Occasional and non-tolerable.	2
	Constant and non-tolerable.	3
15.	*Sadan* (Fatigue)	
	No fatigue.	0
	Fatigue occasionally on doing heavy work.	1
	In carrying out routine work	2
	Even without doing work.	3

C. Interventions

Group A - Each Patient will be advised for taking *Panchamrita Parpati* (Capsule form) in the dose of 250 mg with Normal water twice daily for 28 days.

Group B - Each Patient will be advised to take a Placebo (1 capsule) with normal water twice daily for 28 days.

Both Groups

In both groups *Pathya-Apathya* i.e. Specific diet (*Ahara*), and lifestyle modifications (*Vihara*) will be advised which is necessary for the management of *Grahani Roga* in every patient.

Statistics

The subjective parameters will be analyzed. The 30 patents in every group will be studied. Unpaired t-test will be applied on the collected data to achieve p value of 0.05.Detailed statistical plan will be developed before data analysis using SPSS and MS Excel.

III. DISCUSSION

In this trial, the efficacy of *Panchamrut Parpati* and Placebo in the treatment of *Grahani* is compared for the first time. IBS brings a very negative effect on the quality of life of a sufferer which is mostly underestimated by his/her family as well as co-workers. Patients face a lot of struggles in dealing with day-to-day activities. IBS has unpredictable symptoms, which are physically uncomfortable and very embarrassing for the patient. It decreases the patient's skills as he/she is not capable to concentrate on work with full energy because he/she is always surrounded by a sense of fear due to IBS symptoms. The patient shows less interest in social activities, can not plan any trips with friends, and even can't enjoy favorite meals. Sometimes due to bloating, gastric distention becomes a problem that not only affects the look of the person but also interferes with the person's choice of wearing clothes. The patient has to carry medication at every place. This hectic lifestyle has a very bad impact on the mental status of the patient which converts into many mental illnesses like anxiety, depression, stress, etc. All these things also affect one's relationship with a partner, relatives, and friends. Almost 10-15% population nowadays is suffering from IBS. As we know the exact cause of IBS is still not known in the allopathic medicine system and the treatment adopted is only symptomatic. The allopathic formulations may give instant relief for some time but have no permanent cure for the disease and may also have many adverse effects on the body. But the psychosomatic aspect of the diseases cannot be ignored. Also, IBS shows a significant placebo response of up to 40-50% in different clinical trials.[8] Placebo by acting at a psychological level helps to relieve symptoms up to much extent. In Ayurveda, IBS can be correlated with *Grahani roga*. Keeping in view of the above limitations and side effects this study has been chosen to fill this gap of providing a safe and effective line of treatment as Ayurveda provides multiple formulations for this. In Ayurveda *Panchamrita Parpati* mentioned in *Bhaishjya Ratnawali*[9] is advised to be given to the patients of *Grahani roga*. In *Graghani roga* the principal concern is the restoration of *agni*. In Ayurveda *Parpati Kalpana* is specifically indicated for the disorders of GI tract. The process of preparation of *parpati* is a *sanskara* provided through *agni* due to which it gains *ushna guna* and *deepan* properties[10] along with it is *grahi* in nature. There are various *parpaties* mentioned in Ayurvedic texts. But *Panchamrut parpati* is especially considered a drug of choice in the management of *Grahani roga* by *Bhaisjya ratanawali*[11] because *Panchamruta parpati* has *Sudha Gandhaka, Sudha Parada, Loha bhasma, Abhraka bhasma, Tamra bhasma. Sudha Parada* has *Shada rasa, usna veerya,* it is *snigdha, sara and guru* in *Gunas*[12]. *Sudha Gandhaka* is *usna* and *agnikari*[13]. *Loha bhasma* is *rasayan* and *sarva vyadhi hara*[14]. *Abhraka bhasma* is *Trodoshashamaka.Vahnisandeepana*[15]. *Tamra bhasma* is *tikta kasaya* in *rasa*, *madhura* in *vipaka*, *usna* in *veerya*[16]. *Panchamrut parpati* is a preparation made up of *sanskar* provided through *agni*. So after *sanskar*, it becomes rich in *deepan pachana* properties along with *ushna guna* which enhances the appetite. *Panchamrut parpati* is *laghu, ruksha* in *guna*, *tikta* in *rasa*, and *ushna* in *veerya* thus increasing the absorption of *poshak rasa* by opening the intestinal ducts as it penetrates up to minute *srotas*. By its *guna* and *karmas* it pacifies *vata dosha* thus convert the *atiparvarti* of mala into *samyaka parvarti*. Due to its *deepan* and *grahi* properties, it improves the absorption of nutritive substances and provides relief in associated symptoms like *Pandu, svayathu, gulma,* etc. In *Bhaisajya ratnawali*, *Sangrahani rogadhikara* it is said that *Parpati* is *doshaghana, jantughana* and *balya* for digestive system. It reduces the inflammation and irritation of colon mucosa by reducing laxity. Hence all these *gunas* of *Panchamrut parpati* make it very efficient in doing *samprapti vighatana* of *Grahani roga*[17]. So *Panchamrita parpati* is *yogavahi, agnideepaka, grahi* and is selected for the study. So here an effort is made to see whether *Pachamrutparpati* or Placebo treatment is more effective in the management of *Grahani*.

A. Status of trial

Patients are being recruited for the trial.

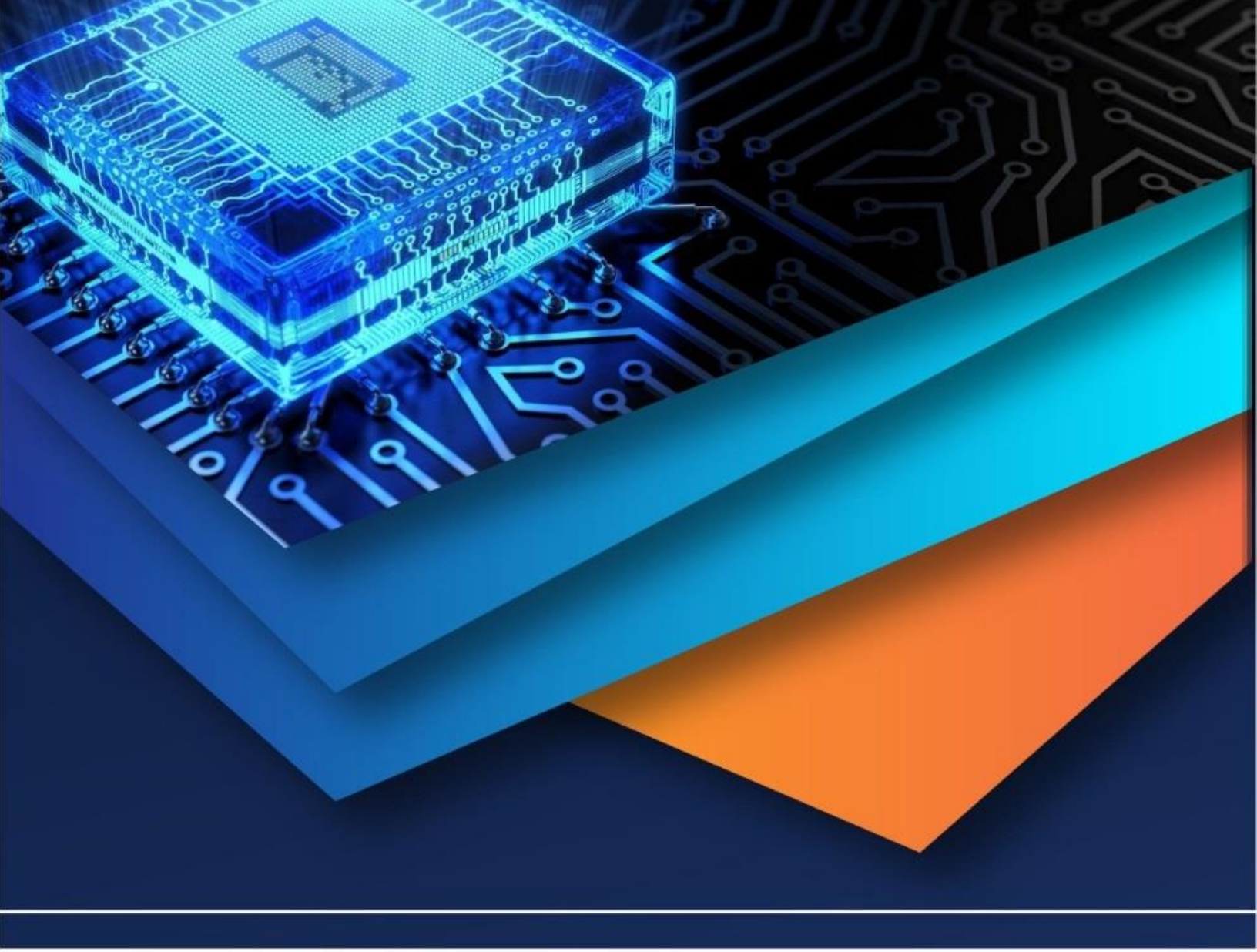
B. Declarations

1) *Ethics approval and Consent to Participate:* The Ethics Committee of Shri Krishna Ayush University, Kurukshetra, accepted the study (SKAU/ Acad/2022/6758).
2) *Financial Implications:* The financial allotment shall be given by Shri Krishna Ayush University for the study will be utilized andwill be completed within the financial limit provided by the institute.
3) *Followed Guidelines:* The common guidelines for clinical trials, known as the Declaration of Helsinki, are being followed in the conduct of this trial.

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