



ISSN 2456-3110

Vol 9 · Issue 12

December 2024

Journal of
**Ayurveda and Integrated
Medical Sciences**

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences



Maharshi Charaka
Ayurveda

Indexed

Study Protocol of an Open Label Randomized Comparative Clinical Trial to evaluate the efficacy of *Shodhana Basti* over *Isabgol Husk* in the management of *Mala Avruta Pakvashayagata Vata* (Chronic Functional Constipation)

Balyogeshwar Sharma¹, Ashish Mehta²

¹PhD Scholar, Dept. of Panchakarma, Shri Krishna Ayush University, Kurukshetra, Haryana, India.

²Professor & H.O.D, Dept. of Panchakarma, Shri Krishna Ayush University, Kurukshetra, Haryana, India.

ABSTRACT

Background: Constipation is used to describe symptoms that relate to difficulties in defecation. Contemporary laxatives, which are generally used in Constipation, become habitual after some duration and gives only symptomatic relief. So, it is a need of hour to search effective, safe & alternative formulations in Ayurveda, which can completely break the pathogenesis of *Mala Avruta Vata*. The formulation used in this study, i.e., *Shodhana Basti* is indicated for the treatment of *Mala Avruta Pakvashayagata Vata*. **Objective:** The Primary aim is to assess the effect of *Shodhana Basti* in the management of *Mala Avruta Pakvashayagata Vata*. The Secondary aim is to compare the efficacy of the *Shodhana Basti* and *Isabgol Husk* in *Mala Avruta Pakvashayagata Vata*. **Methods:** This ongoing study is an open-label randomized controlled interventional trial, with a sample size of 98 both in the trial and standard control group (including dropouts, 10%). Participants in the trial group will receive *Shodhana Basti* in the *Kaala Basti* pattern for a period of fifteen days. The participants in the control group will receive 5gm of *Isabgol husk (Plantago ovata)* in 200 ml of lukewarm water twice a day for 15days. **Outcome Measures:** The primary outcome will include the mean change in the symptoms of *Mala Avruta Vata* assessed by "Bristol stool form scale" and *Pureeshavruta Vata* assessment scale. The secondary outcomes will include the effectiveness of *Shodhana Basti* in the management of *Mala Avruta Vata* than *Isabgol Husk*. **Ethics:** Ethics approval was taken from the Institutional Ethics Committee following which recruitment will be commenced in January 2025. **Clinical Trial Registration:** CTRI/2024/10/075705 dated 23.10.2024

Key words: *Shodhana Basti, Constipation, Isabgol Husk, Malabhadhata, Vibandha.*

INTRODUCTION

Constipation is used to describe symptoms that relate to difficulties in defecation. These include infrequent bowel movements, hard or lumpy stools, excessive straining, sensation of incomplete evacuation or blockage and, in some instances, the use of manual manoeuvres to facilitate evacuation. Symptoms may

be acute, where they typically last less than a week and are commonly precipitated by a change in diet and/or lifestyle (e.g. reduced fibre intake, decreased physical activity, stress, toileting in unfamiliar surroundings). In contrast, chronic constipation is generally defined by symptoms that persist for at least 3 months.^[1]

Constipation is a common gastrointestinal complaint in apparently healthy population as well as in patients with various predisposing disorders with approximately 12 to 19% global prevalence.^[2] The high prevalence rate, economic burden, and adverse implications on the quality of life and the health state make constipation a major public health issue.^[3,4]

Functional constipation is the most common form of constipation. The "Rome III criteria" is a widely accepted format for diagnosis of Functional Constipation.^[5,6] Treatment of constipation is most often empirical. Simple, helpful measures include patient education, dietary fibre supplementation,

Address for correspondence:

Dr. Balyogeshwar Sharma

PhD Scholar, Dept. of Panchakarma, Shri Krishna Ayush University, Kurukshetra, Haryana, India.

E-mail: vasisth.yogi3@gmail.com

Submission Date: 12/11/2024 Accepted Date: 24/12/2024

Access this article online

Quick Response Code



Website: www.jaims.in

DOI: 10.21760/jaims.9.12.16

adequate fluid intake, and regular physical activity.^[7] Patients are evaluated and treated for stress and other psychosocial factors and for problems of chronic abdominal pain.^[8] Patients of constipation not benefited by the lifestyle and dietary modifications may benefit from the judicious use of suitable laxative. Various drugs such as bulk-forming agents (polycarbophil and methylcellulose), stimulants (docusate, bile acids, phenolphthalein, bisacodyl, sodium picosulfate, and ricin oleic acid), stool softeners (docusate and docusate calcium), and osmotic agents (magnesium or phosphate salts, lactulose, sorbitol, glycerine suppositories, and polyethylene glycol) are used depending upon the chronicity and severity of the condition.^[6,7] Pelvic floor retraining may be helpful in the management of patients with outlet delay. Selective patients with the intractable constipation may benefit from surgery.^[7] However, surgery may have serious complications and hence, is least advised.^[9] Though the conventional treatment is well established and safe, it does not provide satisfying improvement for many patients prompting their interest in other therapeutic strategies.^[10] Stimulant, osmotic and saline laxatives of chemical origin are known to cause abdominal cramping, hypokalaemia, flatulence, abdominal distension, and alteration in electrolyte transportation which limit the long-term use of these drugs.^[7]

Contemporary laxatives, which are generally used in Constipation, become habitual after some duration and gives only symptomatic relief. Moreover, these medicines never alter pathogenesis of disease. So, it is a need of hour to search effective, safe & alternative formulations in Ayurveda, which can completely break the pathogenesis of *Mala Avruta Vata*.

The formulation used in this study, i.e., *Shodhana Basti* is indicated for the treatment of *Mala Avruta Pakwashayagata Vata*.^[11] With this idea present study is planned to evaluate the effect of *Shodhana Basti* in *Mala Avruta Pakwashayagata Vata*.

Mala Avruta Vata is considered to be one of the health ailments which have become quite common these days. These chronic patients visited to many physicians

and experts for their chronic symptoms and usually had prescribed laxatives, stool softener or patient itself takes medicine over the counter of the chemist shop. But mild laxative, antacids and all other drugs of acid peptic disorder allow temporary relieve to symptoms but the patients may get habitual to the medicines and then patient won't respond to the medicine and the physiological homeostasis of large intestine gets disturbed.

REVIEW OF LITERATURE

Historical Review

Acharya's have mentioned *Pakwashaya* as the *Vishesha Sthana* for the *Vata Dosh*.^[12] *Acharya Charaka* while describing different *Srotomoola* mentioned *Purishavaha Srotas* as principal organs as *Pakwashaya* and *Guda*.^[13] Large intestine begins from caecum. *Pakwashaya* is interpreted as large intestine is justified over here. *Arunadatta* explained that the organ where *Purisha* is formed is called *Pakwashaya* and it supports *Purisha*. While describing '*Kala*' *Acharya Susrutha* states that this is fifth '*Kala*' which helps to divide *Mala* or excretory products and it is located in *Pakwashaya*.^[14] *Acharya Susrutha* in *Nidana Sthana* spells out that expulsion of various kinds of defecation, urination, expulsion of semen, expulsion of baby, menstruation etc. are dependent on the proper functioning of Large intestine due to its inseparable relationship with *Apana Vayu*.^[15]

In the context of *Acharya's*, *Acharya Susrutha* in *Shareerasthana*, quoted that *Pakwashaya* lies below the *Pittashaya*.^[16] and while explaining the location of *Doshas*, he also quoted that the *Pakwashaya* exists above the *Guda, Shroni* and below the *Nabhi*.^[17]

Pakwashayagata Vata is a condition of aggravated *Vata* in *Pakwashaya* i.e., the large intestine. According to *Acharya Susrutha*, *Vata* aggravated in *Pakwashaya* produces gurgling noise in the abdomen, pain around the umbilicus, difficulty in elimination of urine and faeces, flatulence and pain in the back.^[11] According to *Acharya Charaka* there occurs gurgling sound in the intestine, colic, meteorism, difficulty in micturition and defecation, constipation and pain in the back.^[18]

According to *Acharya Vagbhata*, *Vata* aggravated in *Pakwashaya* gives rise to colic, flatulence, gurgling sound in the intestine, obstruction to movement of faeces, urinary calculi, enlargement of scrotum (hernia), haemorrhoids, catching pain in the lower part of the back, back and waist and other diseases concerned with the lower part of the body.^[19] According to *Acharya Yogaratnakara*, if aggravated *Vata* is located inside *Pakwashaya*, *Antrakoojana* (intestinal sounds), *Shoola* (colic), *Atopa* etc. diseases are produced along with difficulty in passing of urine and faeces, *Anaha* and pain in lumbar region.^[20] According to *Madhava Nidana*, there is intestinal gurgling and pain, difficulty for micturition and defecation, distension of abdomen and pain in the sacral region.^[21]

Chronic constipation can be correlated with *Pureesha Avrita Vata*^[22] which is defined as the absolute constipation along with *Parikartika* (Fissure in Ano), *Shroni Vankshana Prstha Ruk* (pain in hips, groin and back) and uncomfortable sensation in chest region etc.

As per Ayurveda, *Vata Dosha* and *Pureesha Mala* are the main factor involved in this condition. Therefore, the prime treatment principle recommended by Ancient Acharyas is *Snigdha Udavartahara Kriya*.

Ayurvedic Review (Disease)

Acharya Dalhana states that there are two categories of *Pakwashaya*: *Pittashaya* and *Vaatashaya*. *Pittashaya Gata Vata* is the appropriate time to offer *Snehavirechana* with *Eranda Taila* or *Tilwaka Ghrita*. *Vata* received *Avarna* with *Pitta*, *Kapha*, and *Mala* in *Vaatashaya*.^[23] According to *Charaka*, the symptoms of *Pureesha Avruta Vata* include excessive constipation, cutting pain in the anorectum, fast digestion of *Snigdha* substances, *Anaha* after meals, difficulty and delay in passing hard stool due to pressure from food, pain in the hips, groins, and back, and *Vayu* moving in the upward direction, which can harm the heart.^[24] *Charaka* states that the symptoms of *Pittaavruta Apana Vata* include feeling of heat in the anus and penis, *Haridra* (deep yellow) colour of the urine and faeces, and heavy menstrual discharge. *Kaphaavruta Apana Vata* is characterized by poorly formed stool,

heavy in nature, *ama* and *kapha* associations, and the emergence of *Kaphaja Meha*.^[25]

Modern Review (Disease)

Constipation is a common gastrointestinal condition characterised by unsatisfactory defaecation as a result of infrequent stools, difficult stool passage, or both.^[26] Mentioned as a clinical entity by the Egyptians in the 16th century BC,^[27] constipation continues to negatively impact quality of life and generate major healthcare-associated costs. The term functional constipation (FC) has been proposed and defined by the Rome Foundation to help standardise the diagnosis of chronic constipation in the absence of physiological abnormality.^[28,29] As in most other disorders of brain-gut interaction, functional constipation is more prevalent in females. In addition, the prevalence increases slightly with age and is modestly increased in those with a lower socioeconomic status. Functional constipation is of primary origin and is in principle a symptom-based diagnosis. Currently, from a pathophysiological point of view, different subtypes are-

Primary or functional: An entity in which the cause of constipation cannot be identified from the clinical history and physical examination.^[30] Following functional tests, primary constipation may be further classified as: Normal transit constipation (NTC); Slow transit constipation (STC), colonic inertia; outlet obstruction or pelvic floor dysfunction; and combined causes (slow transit constipation and pelvic floor dysfunction). Nullens *et al.* evaluated 1411 patients with chronic constipation at a medical centre and found that 68% had constipation with normal transit, 27.6% with outlet obstruction and 4.3% with slow transit or colonic inertia.^[31]

Secondary or organic: Constipation for which the clinical assessment and workup identifies intestinal or extra-intestinal abnormalities, metabolic or hormonal factors and medications as responsible for the defecatory disturbances.^[32]

Intestinal: Tumour's, diverticulitis, inflammatory strictures, ischemia, volvulus, endometriosis,

postoperative strictures, anal fissure, thrombosed haemorrhoids, mucosal prolapse, ulcerative proctitis.

Medication-induced: Antidepressants, antiepileptics, anti-histamines, antispasmodics, anticholinergics, calcium channel blockers, calcium and iron supplements, and non-hormonal anti-inflammatories.

Metabolic diseases: Hypothyroidism, hypoparathyroidism, hypercalcemia, hypokalaemia, hypomagnesemia, diabetes mellitus, uremia, and heavy metal poisoning.

Neuropathies: Medullar lesions or neoplasia, cerebrovascular disease, multiple sclerosis, autonomic neuropathy and Parkinson's disease.

Myopathies: Amyloidosis and scleroderma.

Other conditions: Chagas disease, cognitive impairment, immobility.

Drug Review

Acharya Dalhan states that *Shodhana Basti* is the treatment for *Mala, Pitta & Kapha Avruta Vata* having *Kashaya, Kalka, and Sneha* accordingly. So, the treatment of *Mala Avruta Vata* is *Shodhan Basti* having *Vidari Kalka, Sneha* and *Kshara. Basti* should be *Vyakta Ushna* at the time of administration.^[23] Acharya Charaka mentioned the *Pakwashaya Shodhana Basti* having *Kashaya Dravya* of *Madanaphala, Jimutaka, Ikshavaku, Dhamargava* and *Kutaja*.^[33] Charaka states that *Udavarta Chikitsa* should be followed for treating *Pakwashayagata Vata*.^[34]

AIM OF STUDY

To evaluate the efficacy of *Shodhana Basti* over *Isabgol Husk* in the management of *Mala Avruta Pakvashayagata Vata*

OBJECTIVES OF STUDY

A. Primary

To assess the effect of *Shodhana Basti* in the management of *Mala Avruta Pakvashayagata Vata*.

B. Secondary

To compare the efficacy of the *Shodhana Basti* and *Isabgol Husk* in *Mala Avruta Pakvashayagata Vata*

METHODOLOGY

Type of Study - Clinical Study

Research Design: An Open Label Randomized Comparative clinical trial

Source of Data - Patients with symptoms of Functional constipation fulfilling the inclusion criteria.

- Participants - OPD & IPD of BKNAGC & Hospital, Narnaul
- Clinical Source - CRF
- Literary Source - Ayurvedic Texts, Research articles, thesis, papers
- Type Of Study - Interventional

Diagnostic criteria - Rome III diagnostic criteria for functional constipation

Inclusion Criteria

1. Patients meeting the "Rome III diagnostic criteria for functional constipation" [patients presenting with two or more of the following for the last three months with symptom onset at least six months prior to diagnosis: (a) Straining during at least 25% of defecations, (b) Lumpy or hard stools at least 25% of defecations, (c) Sensation of incomplete evacuation at least 25% of defecations, (d) Sensation of anorectal obstruction/blockage at least 25% of defecations, (e) Manual manoeuvres to facilitate at least 25% of defecations, e.g., digital evacuation, support of the pelvic floor, (f) Fewer than three defecations per week and those in whom loose stools were rarely present without the use of laxatives] were included.
2. Patients with a stool form score ranging from 1 to 3 on the "Bristol Stool Form Scale"
3. Patient with the symptom of *Mala-Avruta Vata*
4. Sex: Male & Female
5. Age: 20 to 60 Years.
6. Patient ready to give written consent

Exclusion Criteria

1. Patients on chronic laxative medication (>60 days) and/or who were on medications known to cause constipation (like opioid analgesics,

antidepressants, i.e., amitriptyline and imipramine, anticonvulsants, and aluminium-containing antacids) were excluded.

2. Those with functional gastrointestinal disorders other than Functional constipation (i.e., IBS, Belching disorders, etc.) were also excluded.
 3. Patients with a history of abdominal or anorectal surgery in the past one year and those with renal or liver dysfunction or colonic inertia or structural abnormalities of gastro-intestinal tract or uncontrolled systemic ailments (like Human immunodeficiency virus, Diabetes mellitus, and Tuberculosis) or neurological problems (like Parkinson’s disease, multiple sclerosis, sacral nerve damage, and paraplegia or autonomic neuropathy) were excluded.
 4. Pregnant (pregnancy assessed by urine pregnancy test) or lactating women were excluded.
 5. Patients allergic to any of the ingredients of the study medication were excluded.
 6. Patients not willing for clinical trial.
 7. Patients of neoplastic condition
 8. Patients in whom *Basti* is contraindicated
 9. Patient of secondary intestinal constipation will be excluded
- **Withdrawal criteria:** due to ADR, Emergency condition
 - **Sample size:** 98 (44 in each group + considering 10% Dropouts)

In Control Group-49, In Trial Group-49

- **Sampling technique:** Probability Sampling by generating random number sequence using related software
- **Blinding techniques study:** No
- **Random allocation method:** SNOSE
- **Name and place where the study will be conducted:** BKNAG & Hospital, Patikara, Narnaul
- **Criteria of Assessment:** The main symptoms and associated symptoms of functional constipation will be assessed using the Visual Analogue Scale

(VAS scores ranging from 0 to 100 mm) grading constipation from "0" ("no problem at all") to "100" ("terrible problem") and Bristol stool form scale. The patient will provide with a diary card to note down the details of his/her daily bowel evacuations and other symptoms.

- Assessments will be conducted on baseline visit, as well as on days 7th, 15th, 30th, 45th, and 60th day following the end of treatment.
- Assessment scale of *Puresha Avrita Vata* will be used to assess the classical sign and symptoms of *Mala Avruta Vata*.

Table 1: Assessment scale of classical sign and symptoms of Mala Avrita Vata^[35]

No Problem - 0 score, Some Problem - 1 score, Severe Problem - 2 score

SN	Lakshana	BT	During Treatment		After Treatment		
		Zero Day	7 th Day	15 th Day	30 th Day	45 th Day	60 th Day
1.	Absolute Constipation						
2.	Instantaneous digestion of the ingested fat						
3.	Pain in Hips, Groin and Back						
4.	Upward movement of vata in abdomen						
5.	Uncomfortable sensation in chest region						
	Total						

Grouping

1. **Control Group:** Patients will be advised to mix 5gm of *Isabgol Husk* (*Plantago ovata*) in 200 ml of

lukewarm water, stir well, and consume immediately twice a day for 15days.

- 2. Trial Group:** Trial group participants will get *Shodhana Basti* in the *Kaala Basti* pattern for a period of fifteen days. Trial Group Intervention Pattern:

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
AB	NB	AB	NB	AB	NB	AB	NB	AB	NB

Day11	Day12	Day13	Day14	Day15
AB	NB	AB	AB	AB

Follow-Up: After that follow-up will be conducted on 30th, 45th and 60th day. They will allow to report for a scheduled visit after maximum of three days from the scheduled date. Those reporting later than this grace period will be considered as dropouts.

Interventions

Procedure/ Drug: *Shodhana Basti* (*Dalhana Tika* on *Su.Chi.4/5*)

Table 2: Composition of *Shodhana Basti*

<i>Basti Dravya</i>	Ingredients	Quantity
<i>Kwatha Dravya</i>	<i>Madanaphal, Vatsaka, Trivruta, Aaragwadha, Lodhra, Danti</i>	8 Pala (320ml)
<i>Kalka</i>	<i>Putoyanyadi Churna</i>	2 Pala (80gm)
<i>Sneha</i>	<i>Murchita Tila Taila</i>	6 Pala (240ml)
<i>Madhu</i>	-	4 Pala (160ml)
<i>Prakshepa</i>	<i>Gomutra</i>	4 Pala (160ml)
<i>Saindhava</i>	-	1 Aksha (10gm)
	Total	960ml
<i>Anuvasana Basti</i>	<i>Murchita Tila Taila</i>	120ml

Preparation of *Basti Dravya* and procedure of *Basti* will be done according to description available in text.

Time Period need for completion of study per patient - 60 days

Expected Outcomes

- Primary outcome:** *Shodhana Basti* will show improvement in the symptoms of *Mala Avruta Vata* assessed by "Bristol stool form scale" and *Pureeshavruta Vata* assessment scale. Husk.
- Secondary outcome:** *Shodhana Basti* will be more effective in the management of *Mala Avruta Vata* than *Isabgol*

Statistical Software and test to be used: as required.

Statistical analysis: at 95% confidence interval, 5% Type I error and 80% power of the study

Data analysis: A detailed Case Performa will be prepared according to protocol of study and all the parameters will be given suitable scoring depending upon their severity for assessment of efficacy of treatment. The data will be statistically analysed by and will be presented in the form of dissertation.

REFERENCES

- Lacy BE, Mearin F, Chang L, et al. Bowel disorders. *Gastroenterology*. 2016;150(6):1393-1407.
- Peppas G, Alexiou VG, Mourtoukou E, Falagas ME. Epidemiology of Constipation in Europe and Oceania: A Systematic Review. *BMC Gastroenterol*. 2008;8:5.
- Talley NJ. Definitions, epidemiology, and impact of chronic constipation. *Rev Gastroenterol Disord*. 2004;4:S3-10.
- Dennison C, Prasad M, Lloyd A, Bhattacharyya SK, Dhawan R, Coyne K. The health-related quality of life and economic burden of constipation. *Pharmacoeconomics*. 2005;23:461-76.
- Sung IK. Classification and treatment of constipation. *Korean J Gastroenterol*. 2008;51:4-10.
- Rao SS. Constipation: Evaluation and treatment. *Gastroenterol Clin North Am*. 2003;32:659-83.
- Marshal JB. Chronic constipation in adults: How far should evaluation and treatment go? *J Postgrad Med*. 1990;88:49-51, 54, 57-9, 63.
- Johnson DA. Treating chronic constipation: How should we interpret the recommendations. *Clin Drug Investig*. 2006;26:547-57.

9. Ahlquist DA, Camilleri M. Diarrhea and Constipation. In: Kasper DL, Braunwald E, Fauci AS, Hauser S, Longo D, Jameson JL, editors. Harrison's Principles of Internal Medicine. Vol. 1. New York: McGraw-Hill Medical Publishing Division; 2004. p. 231-3.
10. Bongers ME, Benninga MA, Maurice-Stam H, Grootenhuis MA. Health-related quality of life in young adults with symptoms of constipation continuing from childhood into adulthood. *Health Qual Life Outcomes*. 2009;7:20.
11. Susruta, Acharya YT. Susruta Samhita with Nibandhaangraha Commentary by Dalhana and Nayachandrikapanjika of Gayodasa Acharya on Susruta Samhita of Susruta. Nidanasthana; Vatavyadhinidanam: Chapter 1, Verse 23. Reprint ed. Varanasi: Chaukamba Publications; 2014. p. 261.
12. Vagbhata, Sastri Sadasiva Hari. Astanga Hridya with Sarvangasundari commentary of Arunadutta and Ayurvedarasayana Commentary of Hemadri on Astanga Hridya of Vagbhata. Sutrasthana; Doshabhedeeyam: Chapter 12, Verse 1. Reprint ed. Varanasi: Chaukamba Publications; 2014. p. 192.
13. Agnivesha, Charaka, Dridabala, Acharya YT. Charaka Samhita with Ayurveda Deepika Commentary by Chakrapanidutta on Charaka Samhita of Agnivesha. Vimanasthana; Srotasam Vimanam: Chapter 5, verse 8. Reprint ed. Varanasi: Chaukamba Sanskrit Sansthan; 2014. p. 250-1.
14. Susruta, Acharya YT. Susruta Samhita with Nibandhaangraha Commentary by Dalhana and Nayachandrikapanjika of Gayodasa Acharya on Susruta Samhita of Susruta. Sharirasthana; Garbhavyakaranam Shariram: Chapter 4, Verse 16. Reprint ed. Varanasi: Chaukamba Publications; 2014. p. 356.
15. Susruta, Acharya YT. Susruta Samhita with Nibandhaangraha Commentary by Dalhana and Nayachandrikapanjika of Gayodasa Acharya on Susruta Samhita of Susruta. Nidanasthana; Vatavyadhinidanam: Chapter 1, Verse 19. Reprint ed. Varanasi: Chaukamba Publications; 2014. p. 261.
16. Maharashisushrutha, Sushruta Samhita with Nibandha Sangraha Commentary of Dalhana Acharya. Edited by Vaidya Jadavji Trikamji Acharya; 8th ed. Varanasi: Chaukamba Orientalia; 2005. p. 363.
17. Maharashisushrutha, Sushruta Samhita with Nibandha Sangraha Commentary of Dalhana Acharya. Edited by Vaidya Jadavji Trikamji Acharya; 8th ed. Varanasi: Chaukamba Orientalia; 2005. p. 100.
18. Agnivesha, Charaka, Dridabala, Acharya YT. Charaka Samhita with Ayurveda Deepika Commentary by Chakrapanidutta on Charaka Samhita of Agnivesha. Chikitsasthana; Vatavyadhichikitsitam: Chapter 28, verse 28. Reprint ed. Varanasi: Chaukamba Sanskrit Sansthan; 2014. p. 617.
19. Vagbhata, Sastri Sadasiva Hari. Astanga Hridya with Sarvangasundari commentary of Arunadutta and Ayurvedarasayana Commentary of Hemadri on Astanga Hridya of Vagbhata. Nidanasthana; Vatavyadhinidanam: Chapter 15, Verse 7. Reprint ed. Varanasi: Chaukamba Publications; 2014. p. 531.
20. Yogaratnakara. Yogaratnakara with Vaidyaprabha Hindi Commentary by Tripathi Indradev and Tripathi Shankar Daya. Vatavyadhinidanam; Verse 16. 1st ed. Varanasi: Chaukamba Publications; 1998. p. 402.
21. Madhavakara. Madhava Nidanam with Madhukosha Sanskrit Commentary by Srivijayarakshita and Srikanthadatta on Madhava Nidanam of Madhavakara. Nidanasthana; Vatavyadhinidanam: Chapter 22, Verse 14. Reprint ed. Varanasi: Chaukamba Sanskrit Sansthan; 1993. p. 413.
22. Tripathi B. Charak Samhita, Chikitsa Sthana. Varanasi: Chaukambha Orientalia; 2018. Shloka 70-72/28. p. 950.
23. Susruta, Acharya YT. Susruta Samhita with Nibandhaangraha Commentary by Dalhana and Nayachandrikapanjika of Gayodasa Acharya on Susruta Samhita of Susruta. Chikitsasthana; Vatavyadhichikitsitam: Chapter 4, Verse 5. Reprint ed. Varanasi: Chaukamba Publications; 2014.
24. Agnivesha, Charaka, Dridabala, Acharya YT. Charaka Samhita with Ayurveda Deepika Commentary by Chakrapanidutta on Charaka Samhita of Agnivesha. Chikitsasthana; Vatavyadhichikitsitam: Chapter 28, verse 70. Reprint ed. Varanasi: Chaukamba Sanskrit Sansthan; 2014. p. 619-20.
25. Agnivesha, Charaka, Dridabala, Acharya YT. Charaka Samhita with Ayurveda Deepika Commentary by Chakrapanidutta on Charaka Samhita of Agnivesha. Chikitsasthana; Vatavyadhichikitsitam: Chapter 28, verse 229-30. Reprint ed. Varanasi: Chaukamba Sanskrit Sansthan; 2014. p. 626.
26. Ford AC, Moayyedi P, Lacy BE, et al. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. *Am J Gastroenterol*. 2014;109:S2-S26.
27. Ebbell B. The Papyrus Ebers: the greatest Egyptian medical document. Levin & Munksgaard; 1937. p. 30-32.
28. Lacy BE, Mearin F, Chang L, et al. Bowel disorders. *Gastroenterology*. 2016;150:1393-1407.e5.
29. Longstreth GF, Thompson WG, Chey WD, Houghton LA, Mearin F, Spiller RC. Functional Bowel Disorders. *Gastroenterology*. 2006;130:1480-91.
30. Mertz H, Naliboff B, Mayer E. Physiology of refractory chronic constipation. *Am J Gastroenterol*. 1999;94:609-15.
31. Nullens S, Nelsen T, Camilleri M, Burton D, Eckert D, Iturrino J, et al. Regional colon transit in patients with dyssynergic defaecation or slow transit in patients with constipation. *Gut*. 2012;61:1132-9.
32. Lindberg G, Hamid S, Malfertheiner P, Thomsen O, Fernandez LB, Garisch J, et al. World Gastroenterology Organization

global guideline: constipation—a global perspective. J Clin Gastroenterol. 2011;45:483–7.

33. Agnivesha, Charaka, Dridabala, Acharya YT. Charaka Samhita with Ayurveda Deepika Commentary by Chakrapanidutta on Charaka Samhita of Agnivesha. Sidhithana; Bastisidhi: Chapter 10, verse 25. Reprint ed. Varanasi: Chaukamba Sanskrit Sansthan; 2014. p. 725.
34. Agnivesha, Charaka, Dridabala, Acharya YT. Charaka Samhita with Ayurveda Deepika Commentary by Chakrapanidutta on Charaka Samhita of Agnivesha. Chikitsasthana; Vatavyadhichikitsitam: Chapter 28, verse 90. Reprint ed. Varanasi: Chaukamba Sanskrit Sansthan; 2014. p. 621.
35. Singh R, Gulhane JD. Role of Udavartahar Chikitsa in the management of Pureesha Avrita Vata with special reference to Chronic Constipation on Constipation Assessment Scale: A

Case Study. J Ayurveda Integr Med Sci. 2023;8(2):ISSN: 2456-311.

How to cite this article: Balyogeshwar Sharma, Ashish Mehta. Study Protocol of an Open Label Randomized Comparative Clinical Trial to evaluate the efficacy of Shodhana Basti over Isabgol Husk in the management of Mala Avruta Pakvasyagata Vata (Chronic Functional Constipation). J Ayurveda Integr Med Sci 2024;12:132-139.

<http://dx.doi.org/10.21760/jaims.9.12.16>

Source of Support: Nil, **Conflict of Interest:** None declared.

Copyright © 2024 The Author(s); Published by Maharshi Charaka Ayurveda Organization, Vijayapur (Regd). This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by-nc-sa/4.0>), which permits unrestricted use, distribution, and perform the work and make derivative works based on it only for non-commercial purposes, provided the original work is properly cited.