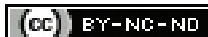


A Comparative Analysis of *Vidarikand Vati* (*Pueraria tuberosa* DC) and *Ashwagandha Vati* (*Withania somnifera* Linn.) for *Karshya* (Underweight): A Randomised Controlled Trial Research Protocol

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ABSTRACT

Introduction: The term “*karshya*” refers to a person who is thin, weak, or malnourished. It originates from the root word “*Tanukarane dhatu*,” which translates to “*Alpa, Suskshma*” (small, subtle). According to *Dalhanacharya*, *Karshya* is characterised by a deficiency in *Upachaya* (growth), *Bala* (stamina), and *Rupa* (appearance). In Ayurveda, *Ahara* (food) is considered the most crucial of the three pillars of health, known as *Tryopasthambha*. Ayurvedic medicine emphasises the concept of *Agni*, the digestive fire, which transforms food into nourishment. Malnutrition occurs due to *Mandagni*, or weak digestive fire, leading to malabsorption and poor digestion. *Karshya* (underweight) is classified into aetiology, prodrome, signs and symptoms, complications, and chronic diseases, and is considered a poor predictor of overall health outcomes.

Need of the study: There are numerous research articles on weight gain. However, many nutritional and bulk-promoting products in the market are expensive and are known to have significant side-effects. *Charaka Samhita* mentions *Vidarikanda* as *balya* (strengthening) and *bruhanika* (growth-promoting). It is

a cost-effective and readily available *bruhanika* herb for weight gain. Despite this, only a few individuals are aware of herbal medications to gain weight. Hence, this study is planned.

Aim: To evaluate the comparative efficacy of *Ashwagandha vati* (*Withania somnifera*) versus *Vidarikand vati* (*Pueraria tuberosa* DC) in the management of *Karshya* (underweight).

Materials and Methods: A double-blind, controlled trial will be conducted at the Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India from April 2025 to February 2026. Sixty patients (30 in each group) who are underweight will be included in this study. Group A (the control group) and Group B (the experimental group) will be treated with *Ashwagandha vati* (*Withania somnifera* Linn) and *Vidarikand vati* (*Pueraria tuberosa* DC), respectively, for 90 days. Patients will be assessed based on Body Mass Index (BMI), body weight, and body circumference (arm and waist) on Day 0, Day 30, Day 60, and Day 90. Statistical analyses will be performed using paired and unpaired t-tests. A p-value <0.05 will be considered statistically significant.

INTRODUCTION

Underweight is described as a BMI below 18.5 kg/m² [1]. According to World Health Organisation (WHO) data from 2016, the prevalence of underweight in adults, defined as BMI below 18.5, was 22.6%-67% for men and 24.1% for women [2]. The root “*Krush Tanukarane*” with “*Acha Pratyaya*” is where the term “*Krush*” originates [3]. *Acharya Dalhana* describes *Karshya* as “*Karshyam Mamsakshayam*,” which denotes a person with a thin body and *krusha* [4]. Both *Krusha* and *Sthula* are regarded as “*Ashtaninditiya*” people, according to *Charaka* [5]. A reference to *Bruhanika Mahakashaya* mentions herbs with *Bruhanika* properties found in the *Charak Samhita*. It contains *ashwagandha* and *vidarikand*. In *Vidarikand*, the doshas of *Vata*, *Pitta*, and *Rakta* are pacified by *Shita Veerya*, *Guru*, and *Snigdha Guna*, which have the quality of *madhura rasa*. Additionally, they possess *madhura vipaka*, which impacts *vatashamaka* [6]. The *brimhana* (growth-promoting) impact in the body is directly attributable to the *guru*, *Snigdha*, and *mrudu* guna. *Vidarikand* is readily available and reasonably priced. *Vidarikand vati* (*Pueraria tuberosa*) is a popular Ayurvedic remedy that strengthens the body and supports all *Dhatu*s (tissues). The flavone present in *Vidarikand* is a free radical scavenger and polyphenol that modulates hepatic cholesterol metabolism and reduces inflammation in the Gastrointestinal Tract (GIT) [7].

Keywords: *Agni, Ahar, Balya, Bruhanika*

Ashwagandha Rasayana has an anabolic (*brimhana*) effect on various tissues in the body. It possesses a sweet (*madhura*) and bitter (*tikta*) taste, a nourishing quality (*snigdha guna*), heating potency (*ushna veerya*), and a sweet post-digestive effect (*madhura vipaka*). This herbal preparation helps soothe *Vata* and *Pitta* doshas while increasing *Kapha*. The *laghu guna* (light quality) of *Ashwagandha* (*Withania somnifera*) aids in stimulating *Agni* and may enhance digestion, absorption, and assimilation of the substance [8].

REVIEW OF LITERATURE

In classical texts, *Bruhanika* gana yields better results for gaining weight. Drugs like *Ashwagandha*, *Shatavari*, *Vidarikand*, and *Kushmand* are mentioned in it [9]. *Vidarikanda* has *madhura rasa* and *madhura vipaka*, which have a *vatashamaka* (*Vata*-pacifying) effect. *Aharpaka* and *vrishtya* properties help in triglyceride synthesis and contribute to *deha-vridhhi* (bodily growth). The flavone present in *Vidarikand* is a free radical scavenger and a polyphenol that modulates hepatic cholesterol metabolism and reduces inflammation in the GIT [9].

Aparna KP et al., conducted a study on underweight children aged two to five years diagnosed with *Karshya*. Participants were randomly assigned to two groups of 15. Group A received *Ghanavyoshadi Khanda* with *Sukoshna Ksheera* before meals, while Group B received

Vidarikanda Khanda with *Sukoshna Ksheera* after meals for one month. Improvements were observed in weight, height, Mid-Upper Arm Circumference (MUAC), and BMI in both groups. Significant enhancements were noted in *Kshut* (appetite) and *Abyavarana Sakti*, with insignificant changes in *Alpapranaschakriya* (constipation), *Pipasa* (thirst), and *Nidra* (sleep). The study concluded that *Ghanavyoshadi Khanda* and *Vidaryadi Khanda*, combined with *Sukoshna Ksheera*, were equally effective in managing underweight in children with *Karshya* [10].

According to a study by Bhagat VV et al., 60 subjects meeting the diagnostic criteria were randomly assigned to two groups of 30 participants each. The experimental group was administered *Vidarikand churn* with 200 mL of milk daily each morning, while the control group received only 200 mL of milk. The treatment lasted 45 days, with follow-up evaluations at 10-day intervals. Improvements were observed in body weight, BMI, and waist circumference. The findings indicated that *Vidarikand* was significantly more effective than the control for individuals classified as underweight [11].

In another study by Singh SK et al., the study group showed significant improvement in weight, indicating accelerated growth, while height improved in both groups, with a higher growth rate in the study group. This supports the efficacy of *Vidarikandadi Churna* in nourishing all *Dhatu*s. The drug enhances *dhatvagni* function, leading to the adequate formation of all *dhatu*s, including *Mamsa* (muscle) and *Meda* (fat), which improves BMI. Key laboratory parameters studied were Haemoglobin (Hb) (g/dL) and total protein, as these are affected by malnutrition [11].

In a study by Sharma S et al., about 30% of the children were malnourished, and *Ashwagandha* churna consumption improved their nutritional status. Further large-scale trials are needed to confirm *Ashwagandha* churna's efficacy in alleviating malnutrition [12].

This study aims to compare the effects of *Vidarikanda* in *vati* form (*Pueraria tuberosa* DC) and *Ashwagandha* in *vati* form (*Withania somnifera* Linn.) in the treatment of *Karshya* (underweight).

Primary objective:

- To evaluate the efficacy of *Vidarikand vati* in patients with *Karshya* (underweight).
- To evaluate the efficacy of *Ashwagandha vati* in patients with *Karshya* (underweight).

Secondary objective:

- To compare the efficacy of *Vidarikand vati* and *Ashwagandha vati* in patients with *Karshya* (underweight).
- To prepare *Vidarikand* and *Ashwagandha* in *vati* dosage form.

Null hypothesis (H_0): *Vidarikand* will not be more efficacious than *Ashwagandha* in improving various parameters, i.e., BMI, body weight, arm circumference, and waist circumference in *Karshya* (underweight).

Alternative hypothesis (H_1): *Vidarikand* will be less efficacious than or equally efficacious as *Ashwagandha* in improving various parameters, i.e., BMI, body weight, arm circumference, and waist circumference in *Karshya* (underweight).

MATERIALS AND METHODS

A double-blind, randomised, standard-controlled trial will be conducted in the *Kayachikitsa* Outpatient Department (OPD) and Inpatient Department (IPD) of Ayurveda College and Hospital Wardha, Maharashtra, India, as well as at specialty camps, from April 2025 to February 2026. Ethics and registration: Approval from the Institutional Ethics Committee (IEC) has been obtained (Reference No. MGACHRC/IEC/Jun-2024/839), and Clinical Trial Registry of India (CTRI) registration has been completed (CTRI/2024/07/071655). Patients will be recruited after obtaining written informed consent. Each patient's confidentiality will be maintained during the study.

Inclusion criteria:

- Patients who have provided written informed consent to participate in the trial, age 20-30 years of either sex, BMI between 14 and 18.5 kg/m² [13] will be included in the study [13].

Exclusion criteria:

- Patients with known hyperthyroidism, Irritable Bowel Syndrome (IBS), tuberculosis, or AIDS.
- Subjects with known systemic diseases (e.g., diabetes, hypertension, chronic kidney disease, chronic heart disease) or other illnesses that affect the immune system (e.g., rheumatoid arthritis, HIV). Hb level less than 8 g/dL. Women with menorrhagia will be excluded from the study.

Sample size calculation: The sample size was calculated using the following formula:

$$n \geq \{ (Z_{(1-\alpha/2)} + Z_{(1-\beta)})^2 (\sigma_1^2 + \sigma_2^2/r) \} / (\mu_2 - \mu_1)^2$$

Alpha (α)=0.05 (Significance level)

- Beta (β)=0.05 (Power=1- β =0.95)

- Mean in Group 1 (*Ashwagandha Vati*): μ_1 =15.89

- Standard deviation in Group 1: σ_1 =1.21

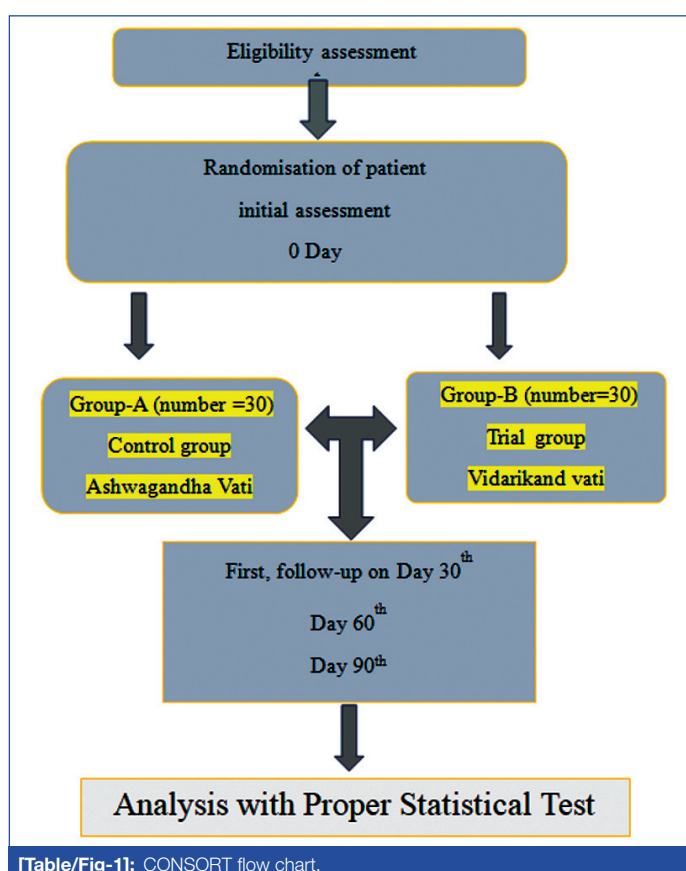
- Mean in Group 2 (*Vidarikand Vati*): μ_2 =17.12

- Standard deviation in Group 2: σ_2 =1.11 [14]

- Ratio of group sizes (Group 2/Group 1): r =1:1

- Using these values, the minimum sample size per group is 24, for a total of 48 participants.

- Assuming a 30% dropout rate, the total sample size should be 60 (30 per group) [Table/Fig-1].



[Table/Fig-1]: CONSORT flow chart.

Study Procedure

Individuals who meet the inclusion criteria will be randomised in a 1:1 ratio into either the trial group or the control group. Randomisation will be conducted using a lottery method. The group assignments will remain concealed until the trial concludes, ensuring that all participants, research assistants, physicians, and other staff are blinded to these assignments. The principal investigator will assess each participant throughout the trial. The blinding codes will be kept

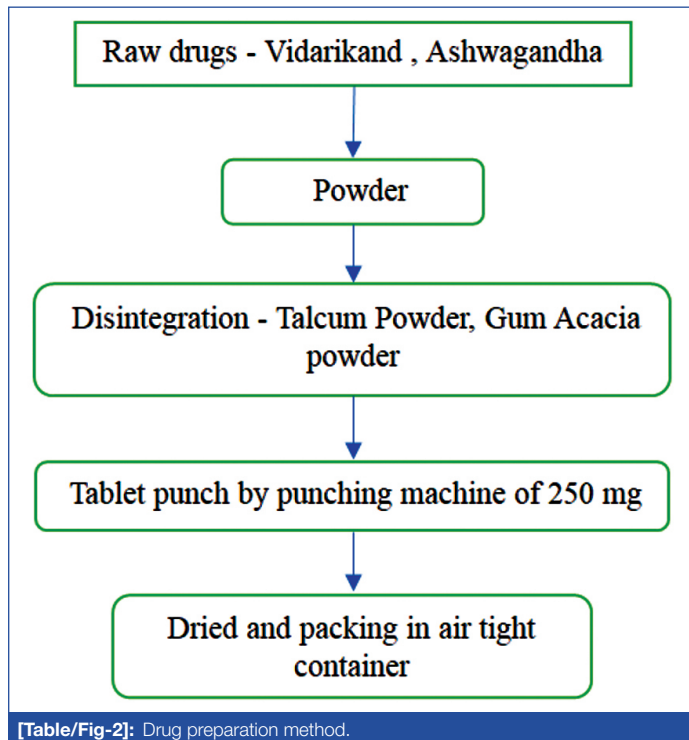
confidential during the entire experiment, and both drugs will be packaged in identical containers. Evaluations of participants will include body weight, BMI, and body circumference (arm and waist circumference) every 30 days.

Drug collection/authentication: The raw materials of *Ashwagandha* and *Vidarikand* (*Pueraria tuberosa* DC) will be procured from reliable sources and authenticated by the Department of *Dravya Guna*, Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod (Hirapur), Wardha, Maharashtra, India.

Detail drug preparation: The medicines will be prepared in the college Rasashala as per the guidelines for medicine preparation [15].

The tablets of the single drugs *Vidarikand* and *Ashwagandha* will be prepared [Table/Fig-2].

The study intervention for both groups is explained in [Table/Fig-3].



S. No.	Size of sample	Intervention group	Dose and frequency	Anupan	Duration	Follow-up during treatment
1.	30	<i>Ashwagandha vati</i>	3 gm twice a day	Milk	90 days	On the 30 th , 60 th , and 90 th day
2.	30	<i>Vidarikand vati</i>	3 gm twice a day	Milk	90 days	On the 30 th , 60 th , and 90 th day

[Table/Fig-3]: Posology.

Primary outcome: The improvement in underweight patients will be assessed on the following parameters:

- Body weight — measured on an empty stomach using a digital weighing machine (Brand Hesley, Weight Limit 180 kilograms) on 0, 30th, 60th, 90th day [13].
 - Body circumference (arm and waist) — assessed on Day 0, Day 30, Day 60, and Day 90.
- Arm circumference: The participant should stand or sit with the arm relaxed and hanging by the side. The midpoint between the acromion and the olecranon will be measured using a flexible, non stretchable measuring tape.
 - Waist circumference: The participant should stand upright, feet hip-width apart, and breathe out normally. The measurement will be taken at the narrowest point between the lower margin of the last rib and the iliac crest. If this is unclear, measure just above the belly button.

- BMI: A measure that helps determine whether a person has a healthy body weight for their height. It will be assessed on Day 0, Day 30, Day 60, and Day 90.

STATISTICAL ANALYSIS

The statistical analysis shall be conducted till using R software. The Mann-Whitney test and Chi-square test will be used for subjective parameters. Additionally, for objective parameters, a t-test will be used for comparisons, with a significance level set at 5%.

Gantt chart is presented in [Table/Fig-4].

Scholar/Investigator	Dr. Nikita Rathod					
Title	Comparative analysis of <i>Vidarikand vati</i> (<i>Pueraria tuberosa</i> DC) and <i>Ashwagandha vati</i> (<i>Withania somnifera</i> Linn.) for <i>Karshya</i> (underweight): A Randomised Controlled Trial					
Procedures	Q1	Q2	Q3	Q4	Q5	Q6
IEC approval						
Literature review						
Preparing drugs						
Patient enrollment						
Information gathering						
Analysis of statistics						
Writing thesis						

[Table/Fig-4]: Gantt chart.

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