

External Application of Varuna (*Crataeva nurvala* Buch-ham) Patra Kalka with Ghrita after the Gomaya Gharshana versus Varuna Patra Siddha Ghrita versus Manjistha Ghrita in the Management of Striae Gravidarum: A Research Protocol for a Three Arm Study

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ABSTRACT

Introduction: Ayurveda emphasises both preventive and curative aspects of disease, with an extensive repertoire of treatments, including those with cosmetic applications. Striae gravidarum, a prevalent dermatological condition, affects 75-90% of pregnant women globally. In Ayurveda, striae gravidarum is referred to as “Kikkisa,” and is attributed to the stretching and tearing of the skin during pregnancy.

Need of the study: Many cosmetic products and procedures claim to improve the appearance of striae; however, most merely alter superficial appearance rather than addressing the underlying physical characteristics of the condition. In some cases, they may even lead to undesirable side effects. Therefore, there is a pressing need to explore safe and reliable treatments grounded in Ayurveda. The external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita*, following *gomaya gharshana*, holds significant potential and is supported by classical textual references for use in the management of striae gravidarum (*Kikkisa*). Despite this, the formulation has not yet been thoroughly evaluated. Hence, the present study aims to document and establish the specific therapeutic effects of this Ayurvedic remedy in the management of striae gravidarum, emphasising both safety and Ayurvedic principles.

Aim: The aim of the present comparative study is to evaluate the efficacy of external application of *Varuna* (*Crataeva nurvala* Buch-Ham) leaf paste with ghee after cow dung rubbing; *Varuna* leaf medicated ghee; and *Manjistha* medicated ghee in the management of striae gravidarum.

Materials and Methods: The present interventional, open-labelled, randomised controlled trial will employ a three-arm study design from June 2025 to September 2026 at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (Hirapur), Wardha, Maharashtra, India. Sixty female participants aged 25-45 years with a history of striae gravidarum will be randomly assigned to one of three treatment groups. Group A: *Varuna patra kalka* with *ghrita* after *gomaya gharshana*; Group B: *Varuna patra siddha ghrita*, and Group C: *Manjistha ghrita*. Treatments will be administered over 8 weeks, with biweekly assessments. Parameters will include subjective evaluations {such as *kandu* (itching), *vidaha* (burning sensation), *twak bheda* (skin tearing), *rekha swaroopa* / *twak sankocha* (linear stretch marks), and *vaivarnya* (discolouration)}, and objective assessments {such as photographic documentation, lesion count, lesion dimensions, and the Patient Scar Assessment Scale (PSAS)}.

Keywords: Ayurvedic management of pregnancy-striae gravidarum, Gomaya powder, Kikkisa, *Rubia cordifolia*

INTRODUCTION

Ayurveda, the ancient science of life, emphasises both preventive and curative aspects of disease and offers a range of drugs with cosmetic properties suitable for dermatological applications. The extensive adjustments in maternal anatomy, physiology, hormonal levels, and metabolic functions required for a healthy pregnancy deeply impact almost every organ and system in pregnant women. Notably, 75-90% of pregnant women globally experience striae gravidarum [1].

Striae represent a common skin condition that does not typically cause significant medical problems but can lead to psychological distress due to their adverse appearance and physical characteristics, such as changes in thickness and suppleness, which are undesirable to those affected. The emergence of striae gravidarum is often associated with over-extension of the skin,

leading to visible linear, pinkish scars due to dermal damage and weakening of elastic tissue.

Kikkisa, as described in Ayurvedic classical texts, refers to the stretching and tearing of the skin during pregnancy, accompanied by symptoms such as *charmavidarana* (tearing of the skin), *kandu* (itching), *vidaha* (burning), *vaivarnya* (discolouration), and *vali utpatti* (formation of stretch marks) [2].

The aetiopathogenesis of *Kikkisa* points towards vitiation of *Vata* and other *tridoshas*; hence, in its management, remedies that are *tridoshaghna*, *dahahara*, *kandughna*, and *varnya* should be selected [3].

Ayurvedic classical texts mention various types of internal and external remedies for the management of *Kikkisa*. Among these, the external application of *Varuna patra kalka* with *goghrita* after

gomaya gharshana, although mentioned in textual references and considered potentially beneficial, has not yet been scientifically evaluated. Hence, the current topic has been selected based on a reference in Bhaishajya Ratnavali [4].

Aim: To evaluate the comparative efficacy of the external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana*, *Varuna patra siddha ghrita*, and *Manjistha ghrita* in the management of striae gravidarum (*Kikkisa*).

Study Objectives

Primary objectives:

- To evaluate the efficacy of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana* in striae gravidarum (*Kikkisa*).
- To evaluate the efficacy of *Varuna patra siddha ghrita* in striae gravidarum (*Kikkisa*).
- To evaluate the efficacy of *Manjistha ghrita* in striae gravidarum (*Kikkisa*).
- To evaluate and compare the efficacy of *Varuna patra kalka* with *ghrita* after *gomaya gharshana* versus *Varuna patra siddha ghrita* and *Manjistha ghrita* in striae gravidarum (*Kikkisa*).

Secondary objectives:

- To study the pharmacognostic, physicochemical, and phytochemical characteristics of the *patra* of *Crataeva nurvala* Buch-Ham.
- To study the physicochemical and phytochemical characteristics of *ghrita*.
- To study the pharmacognostic, physicochemical, and phytochemical characteristics of *Manjistha*.

Null Hypothesis (H0):

- There is no significant difference in efficacy between the external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana* and *Varuna* (*Crataeva nurvala* Buch-Ham) *patra siddha ghrita* in the management of striae gravidarum (*Kikkisa*) over 8 weeks.
- There is no significant difference in efficacy between the external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana*, *Varuna* (*Crataeva nurvala* Buch-Ham) *patra siddha ghrita*, and the control *Manjistha ghrita* in the management of striae gravidarum (*Kikkisa*) over 8 weeks.

Alternate Hypothesis (H1):

- The external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana* has an equal effect compared to *Varuna* (*Crataeva nurvala* Buch-Ham) *patra siddha ghrita* in the management of striae gravidarum (*Kikkisa*) over 8 weeks.
- The external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana* and *Varuna* (*Crataeva nurvala* Buch-Ham) *patra siddha ghrita* has an equal effect compared to *Manjistha ghrita* in the management of striae gravidarum (*Kikkisa*) over 8 weeks.

REVIEW OF LITERATURE

Striae gravidarum, known in Ayurveda as *Kikkisa*, is described in classical texts such as *Charaka Samhita* and *Ashtanga Hridaya* as a condition arising due to displacement of the *tridoshas* during pregnancy, resulting in symptoms like itching (*kandu*), burning sensation (*vidaha*), discoloration (*vaivarnya*), and stretch marks (*rekha*) on the skin. Although not medically serious, this dermal stress condition can be psychologically and cosmetically distressing [5].

Earlier modern studies, such as that by Khatun F et al., established that *Crataeva nurvala* leaves possess significant antioxidant and antimicrobial activities, which may assist in tissue repair and reduce oxidative stress in dermal layers affected by striae [6]. Pharmacological investigations into *Crataeva nurvala* (*Varuna*) validated its antinociceptive and neurobehavioural effects via GABAergic modulation, supporting its systemic safety and potential for topical application. [6] Additionally, Bhattacharjee A et al., (2015) confirmed *Varuna*'s antioxidant and antimicrobial properties, which may contribute to skin regeneration and dermal healing [7].

Similarly, *Rubia cordifolia* (*Manjistha*) has long been revered in Ayurveda for its *raktashodhana*, *varnya*, and *kusthaghna* properties. [8] A comparative clinical study on *Manjistha ghrita* and *go-ghrita* for *Kikkisa* reported significant improvements in symptoms such as itching and pigmentation.

Despite these individual studies, no prior clinical research has directly examined the specific combination of *Varuna patra kalka* with *ghrita* following *gomaya gharshana* as mentioned in *Bhaishajya Ratnavali* (69/5). This creates a distinct research gap, which the present study aims to address.

Thus, from classical Ayurvedic descriptions to modern clinical validations, the understanding of *Kikkisa* has evolved; however, comprehensive comparisons between classical remedies such as *Varuna patra kalka* and *Manjistha ghrita* remain largely unexplored, justifying the rationale and design of the current study.

MATERIALS AND METHODS

An open-labelled, randomised, controlled, three-arm, parallel design clinical study will be conducted in the Department of Obstetrics and Gynaecology OPD (Prasuti Tantra avam Striroga OPD) at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India, patients will also be enrolled through special camps at the nearby locality of Wardha. A total of 60 patients will be recruited for the study. Computer-generated random number table was done for allocation sequence generation, from June 2025 to September 2026. Ethical approval for the study protocol has been obtained from the Institutional Ethics Committee (IEC) prior to commencement of the study, with registration number MGACHRC/IEC/JUN-2024/835 dated 07-06-2024. The trial has been registered on the CTRI website, with reference number CTRI/2024/09/073489. All eligible participants will be provided with detailed information about the study objectives. Subjects will be recruited only after obtaining written informed consent.

Research question:

- Does the external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana* have equal efficacy compared to *Varuna* (*Crataeva nurvala* Buch-Ham) *patra siddha ghrita* in the management of striae gravidarum (*Kikkisa*) over 8 weeks?
- Does the external application of *Varuna* (*Crataeva nurvala* Buch-Ham) *patra kalka* with *ghrita* after *gomaya gharshana* and *Varuna* (*Crataeva nurvala* Buch-Ham) *patra siddha ghrita* have equal efficacy compared to control *Manjistha ghrita* in the management of striae gravidarum (*Kikkisa*) over 8 weeks?

Inclusion criteria:

- Female participants willing to participate, with written informed consent.
- Age between 25-45 years.
- Equal to or greater than 2 years since last delivery.
- No prior treatment for *Kikkisa* within the past 1 month.

Exclusion criteria:

- Pregnant women
- Lactating women
- Any skin diseases other than *Kikkisa*
- Patients with chronic diseases such as tuberculosis, jaundice, etc [1].
- Any malignancy on the affected site

Sample size calculation: Sample size calculation for comparing two means was taken from Dumbare NA et al., (2015) [9].

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

Where: n: Sample size per group.

$Z_{1-\alpha/2}$: Z-score corresponding to the significance level ($\alpha=0.01$)=2.58

$Z_{1-\beta}$: Z-score corresponding to the power (β), $\beta=0.01$: Power=2.33.

$\mu_1=0.8667$: Mean in Group (*Gomaya Churna Udgharshana*)

$\mu_2=1.800$: Mean in Group (*Varuna Patra*)

$\sigma_1=0.571$: Standard deviation in Group (*Gomaya Churna Udgharshana*)

$\sigma_2=0.484$: Standard deviation in Group (*Varuna Patra*)

$r=1$: Equal allocation between groups.

$$(Z_{1-\alpha/2})^2 + (Z_{1-\beta})^2 = (2.576 + 2.33)^2 = 23.86$$

$$\sigma_1^2 + (\sigma_2^2 / r) = 0.571^2 + (0.484^2 / 1) = 0.3260 + 0.2343 = 0.5603$$

$$(\mu_1 - \mu_2)^2 = (0.8667 - 1.800)^2 = (-0.9333)^2 = 0.8711$$

Round up to the nearest whole number: n=16.

Minimum sample size needed per group: 16 and total sample size required: 32.

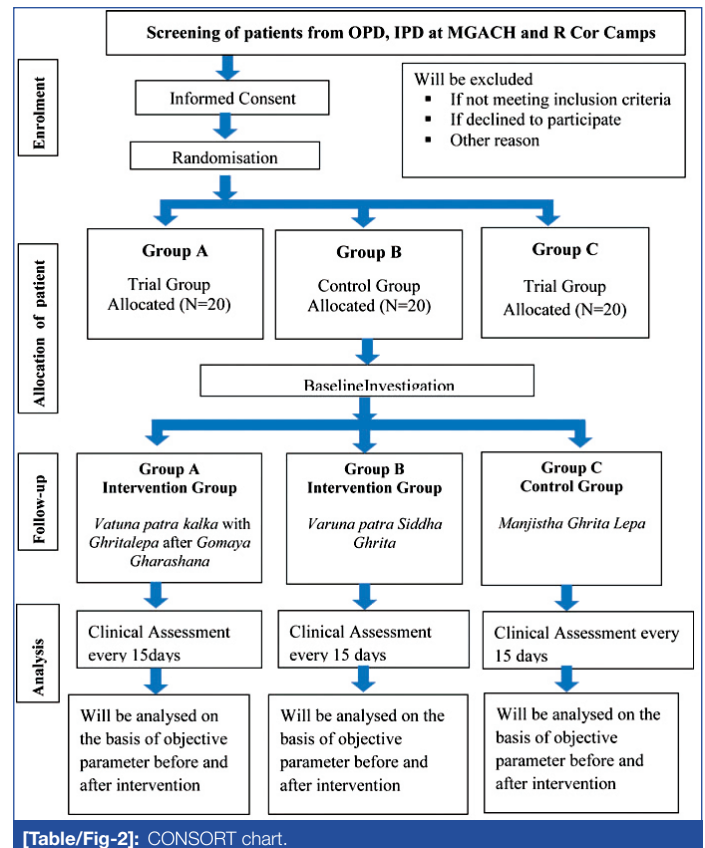
Study Procedure

A total of 60 patients will be recruited and randomly allocated into three groups, with 20 patients in each group. As shown in [Table/Fig-1], Group A (Interventional Group) will receive *Varuna patra kalka* mixed with *ghrita* after *gomaya gharshana* (cow dung friction therapy). Group B (Interventional Group) will be treated with *Varuna patra siddha ghrita*, while Group C (Comparative Group) will receive *Manjistha ghrita* for external application. All treatments will be administered externally for a duration of 8 weeks. A 25% dropout rate has been considered during the study design. The flow of participants through screening, allocation, follow-up, and analysis is described in the CONSORT diagram [Table/Fig-2]. Simple random sampling was applied.

Group	Sample size	Intervention	Dosage form	Dose and frequency	Duration	Follow-up
Group A	20	<i>Varuna patra</i> (<i>Crataeva nurvala</i> Buch-Ham) <i>Kalka</i> with <i>Ghrita</i> lepa after <i>gomaya gharshana</i>	Leaf powder	As per requirement twice a day	8 weeks	14 th days, 28 th days, 42 th days, 56 th days
Group B	20	<i>Varuna patra Siddha Ghrita</i>	Leaf powder	As per requirement twice a day	8 weeks	14 th days, 28 th days, 42 th days, 56 th days
Group C	20	<i>Manjistha Ghrita</i>	Root powder	As per requirement twice a day	8 weeks	14 th days, 28 th days, 42 th days, 56 th days

[Table/Fig-1]: Three groups and their specific intervention with dose and duration.

Intervention description: *Varuna* (*Crataeva nurvala* Buch-Ham) *patra* will be collected, dried, and powdered, and the prepared formulations will be administered to the patient as per the allocated group.



[Table/Fig-2]: CONSORT chart.

Drug collection/authentication: Drugs will be collected from their natural habitat following Good Collection Practices (World Health Organisation (WHO)). Drug authentication will be carried out with the help of Foundation for Revitalisation of Local Health Traditions (FRLHT), Bengaluru; the Botanical Survey of India (BSI) office; the Botany Department or Pharmacognosy Department of any reputed university; or the Dravyaguna Department of an Ayurveda college.

Details of drug preparation [10]:

Varuna Patra Churna: To prepare *Varuna patra churna*, collect and thoroughly clean the *Varuna* leaves. Dry them completely and then grind them into a fine powder. Sieve the powder to ensure uniform consistency and store it in an airtight container, keeping it away from moisture and sunlight for optimal preservation.

Varuna Patra Siddha Ghrita preparation: To prepare *Varuna patra siddha ghrita*, boil *Varuna patra* leaves until the volume is reduced. Strain the mixture to retain only the liquid. Add this liquid to *ghrita* (clarified butter) and cook until the water evaporates, leaving a thickened mixture. Once cooled, store the *ghrita* in an airtight container.

Manjistha Ghrita preparation: The raw materials for *ghrita* preparation include fresh wet paste, oily substances, and liquid media as per the reference. Preparing *ghrita* involves combining the paste, oily substance, and liquid media in specific proportions. This mixture is heated until the liquid evaporates, following the standard criteria for successful preparation of medicated ghee.

To prepare *Manjistha ghrita* specifically, boil *Manjistha* root in water until the volume reduces to one-quarter. Strain the liquid, clarify the *ghrita* (clarified butter), and mix the decoction with the *ghrita*. Heat gently while stirring regularly until fully absorbed. Once cooled, store the *ghrita* in an airtight container.

Assessment Criteria

Clinical features will be assessed using classical Ayurvedic criteria and modified scales referenced in prior literature [11-13]. The screening parameters are summarised in [Table/Fig-3].

S. No.	Clinical features	0	1	2	3	4
1	<i>Kandu</i> (Itching) [11]	No <i>Kandu</i>	Mild <i>Kandu</i> (3-4 times in a day)	Moderate <i>Kandu</i> (5-10 times in a day But not disturbing normal activities)	Severe <i>Kandu</i> (>10 times disturbing normal Activities)	-
2	<i>Vidaha</i> in <i>Udara</i> (Burning sensation) [12]	No <i>Daha</i>	Mild <i>Daha</i> (1-2 times in a day and is ignored by the patient).	Moderate <i>Daha</i> (3-5 times in a day but not disturbing normal activities)	Severe <i>Daha</i> (>5 times also Disturbing normal activities and normal sleep)	-
3	<i>Twak Bheda</i> (Cracking of skin) [12]	No <i>Twak Bheda</i>	Mild <i>Twak Bheda</i> (Middle part of lower abdomen just Shiny)	Moderate <i>Twak Bheda</i> (In the flank of lower abdomen and shiny to glistening type)	Severe <i>Twak Bheda</i> (Wide, flat, depressed or over whole abdomen)	-
4	<i>Rekha Swaroop Twak Sankoch</i> (RSTS) (Linear stretch marks Over abdominal skin) [13]	No RSTS (Normal Skin)	Mild RSTS (Mildly observed on the lower abdomen)	Moderate RSTS, (Near the peripheral region of abdomen)	Severe RSTS (Most of the region of whole abdomen and Causing mental distress)	-
5	<i>Vaivarnyata</i> (Discolouration of skin) [13]	No <i>Vaivarnyata</i> (Normal abdominal skin)	Pinkish	Pinkish-red	Yellowish- white or Purple	Black

[Table/Fig-3]: Screening parameters [11-13].

Objective parameters:

- Illustrative photographs: Pre and posttreatment changes will be documented with the help of a Canon EOS 700D (16-megapixel) camera at a distance of two and a half feet.
- Number of lesions
- Length of lesion (in mm)
- Breadth of lesion (in mm)
- Area of lesion (in mm²)

Patient Scar Assessment Scale (PSAS scale) [14]: For the PSAS, subjects will be required to answer the following six questions:

- Pain: Are the striae painful?
- Itching: are the Striae itching?
- Colour (pigmentation and vascularity): is the colour of the Striae different from the colour of your normal skin?
- Pliability: Is the stiffness of the striae different from that of your normal skin?
- Thickness: Is the thickness of the striae different from your normal skin?
- Relief: Are the striae more irregular than your normal skin?

The following scale will be used:

1= No, not at all (for a and b) / No, as normal skin (for c to f)

10= Yes, very much (for a and b) / Yes, very different (for c to f)

Outcomes:

Primary outcome: Reduction in the severity of striae gravidarum following the external application of *Varuna patra kalka* with *ghrita* after *gomaya gharshana*, *Varuna patra siddha ghrita*, and *Manjistha ghrita*.

Secondary outcome: Changes in characteristics of striae including lesion number, lesion dimensions, and subjective symptoms such as *kandu* (itching), *vidaha* (burning sensation), *twak bheda* (skin cracking), *rekha swaroopa twak sankoch* (linear stretch marks), and *vaivarnya* (discolouration).

Participant timeline: The overall schedule and distribution of research activities are summarised in the participant timeline [Table/Fig-4].

Scholar/Investigator	Dr. Pallavi Dewangan					
Title	Evaluation of comparative efficacy of external application of <i>Varuna</i> (<i>Crataeva nurvala</i> Buch-Ham) <i>patra kalka</i> with <i>Ghrita</i> after the <i>Gomaya Gharshana</i> , <i>Varuna patra siddha Ghrita</i> and <i>Manjistha Ghrita</i> in the management of Striae Gravidarum (<i>Kikkisa</i>): Three Arm study					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Approval from IEC						
Drug Authentication and collection						

Drug Preparation						
Enrolment of the patients						
Data Collection						
Statistical Analysis						
Thesis Writing						
Submission						

[Table/Fig-4]: Gantt chart.

STATISTICAL ANALYSIS

After the study, data will be analysed using suitable statistical tests. Results will be assessed using baseline objective parameters (photographs, number, length, breadth, area of lesions, and PSAS scale). Data will be entered into SPSS software, version 22. Qualitative variables will be compared using the Chi-square test. Analysis of Variance (ANOVA) will be used to compare the means of the three groups with normally distributed data. For before-and-after comparisons, ANOVA will again be used. Mann-Whitney U or Kruskal-Wallis tests will be applied where appropriate, with a significance level of 0.05.

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