

A Clinical and Pharmacological Evaluation of a Nalpamara–Parisha Kashaya Shata-Dhauta Ghrita Based Polyherbal Formulation in the Management of Eczema (Vicharchika)

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Abstract

Eczema, clinically characterized by chronic inflammation, pruritus, erythema, oozing, and lichenification, closely correlates with **Vicharchika** described in Ayurvedic classics under *Kshudra Kushtha*. Vicharchika is predominantly a **Kapha-Pitta pradhana tridoshaja vyadhi**, involving *Rakta*, *Twak*, *Lasika*, and *Mamsa dhatus*.

Conventional treatments for eczema rely heavily on topical corticosteroids and immunosuppressants, which are associated with adverse effects such as skin atrophy, rebound flares, and systemic absorption on long-term use. This underscores the need for **safe, effective, and holistic alternatives**.

Ayurvedic literature documents extensive use of **Kushthaghna, Kandughna, Rakta-shodhana, and Krimighna dravyas**, particularly when processed in *Ghrita*, which acts as a **Yogavahi**, enhancing tissue penetration and bioavailability.

The proposed formulation combines classical **Kushtha-hara herbs** with **Shata-Dhauta Ghrita**, prepared using **Nalpamara and Parisha Kashaya**, aiming to address inflammation, microbial colonization, barrier dysfunction, and chronicity of eczema.

Composition of the Investigational Formulation

Active Herbal Ingredients

- Hydnocarpus pentandra (Tugaraka)**
 - Properties: *Kushthaghna, Krimighna, Tikta-Kashaya rasa*
 - Known for antimicrobial and keratolytic action
- Psoralea corylifolia (Bakuchi)**
 - Properties: *Kandughna, Kushthaghna, Rakta-prasadana*
 - Demonstrates immunomodulatory and melanocyte-stimulating effects
- Cassia alata & Cassia tora (Dadrughna dravyas)**
 - Properties: *Kapha-Pitta shamaka, antifungal, anti-inflammatory*
 - Traditionally indicated in *Dadru* and *Vicharchika*
- Aristolochia bracteata**
 - Properties: *Krimighna, Shothahara*
 - Used in minimal, purified, and regulated quantity following classical Shodhana procedures

- Included for its traditional indication in chronic skin disorders

Base Medium

- **Shata-Dhauta Ghrita** prepared using
- **Nalpamara Kashaya** (*Ficus benghalensis*, *F. religiosa*, *F. racemosa*, *F. microcarpa*)
- **Parisha Kashaya** (*Thespesia populnea*)
This base is known for:
 - *Twak-prasadana*
 - *Vrana-ropana*
 - Restoration of skin barrier integrity
 - Cooling and anti-inflammatory effects

4. Need for the Study

- Lack of standardized clinical evidence for complex Ayurvedic formulations in eczema
- Need to evaluate **safety**, especially for formulations containing traditionally potent herbs
- Increasing demand for steroid-free dermatological therapies
- Opportunity to scientifically validate classical Ayurvedic principles

5. Objectives

Primary Objective

- To evaluate the **clinical efficacy** of the investigational Ayurvedic formulation in reducing the severity of eczema (Vicharchika).

Secondary Objectives

- To assess improvement in **pruritus, erythema, exudation, and lichenification**
- To evaluate **quality of life** improvement
- To assess **safety and tolerability** of the formulation
- To observe changes in **Ayurvedic parameters** such as *Dosha prakopa* and *Twak lakshanas*

6. Hypothesis

Null Hypothesis (H₀): The investigational formulation has no significant effect in the management of eczema.

Alternative Hypothesis (H₁): The investigational formulation significantly improves clinical and symptomatic parameters of eczema with acceptable safety.

7. Study Design

- **Type:** Prospective, open-label, single-arm clinical study
- **Duration:** 8 weeks treatment + 4 weeks follow-up
- **Sample Size:** 30–40 patients (pilot study)

8. Selection Criteria

Inclusion Criteria

- Patients aged 18–60 years
- Diagnosed cases of eczema (Vicharchika)
- Chronicity \geq 3 months

- Mild to moderate severity

Exclusion Criteria

- Severe or infected eczema
- Immunocompromised individuals
- Pregnant or lactating women
- Patients on systemic steroids or immunosuppressants

9. Intervention

- **Mode:** External application
- **Dose:** Thin layer applied twice daily
- **Duration:** 8 weeks
- **Standard dietary and lifestyle advice** based on Kapha-Pitta shamana principles

10. Assessment Criteria

Subjective Parameters

- Kandu (itching)
- Daha (burning sensation)
- Rukshata (dryness)

Objective Parameters

- Erythema
- Scaling
- Oozing
- Lichenification

Scales

- Eczema Area and Severity Index (EASI)
- Visual Analog Scale for itching

11. Safety and Toxicity Monitoring

- Baseline and post-treatment liver and kidney function tests
- Patch test before application
- Monitoring for adverse skin reactions

Special emphasis will be placed on **dose regulation, purification (Shodhana), and pharmacovigilance** due to the inclusion of *Aristolochia bracteata*.

12. Statistical Analysis

- Paired t-test / Wilcoxon signed-rank test
- Significance level set at $p < 0.05$

13. Ethical Considerations

- Approval from the Institutional Ethics Committee
- Written informed consent
- Right to withdraw at any stage

14. Expected Outcomes

- Reduction in eczema severity and recurrence
- Improved skin texture and reduced dependency on steroids
- Establishment of a **safe, classical, ghrita-based dermatological formulation**

15. Scope for Future Research

- Randomized controlled trials
- Comparative studies with standard topical steroids
- Pharmacological and molecular mechanism studies