

Study Protocol for Pharmaceutico-Analytical study and Clinical Evaluation of modified cream form of Sahachara Ghrita on Mukhdushika with special reference to Acne Vulgaris: A Randomized Controlled Trial

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Background: Mukhadushika/Acne vulgaris is a common chronic inflammatory condition of the skin. It is a prevalent issue affecting approximately 80% of teenagers and young adults.[1] Sahachara Ghrita is mentioned in Bhaishajyaratnavali for Mukhadushika.[2] To address the challenges of applying Sahachara Ghrita, a cream formulation is being developed for easier and more convenient application. [3]

Aim: To evaluate the pharmaceutico-Analytical study and clinical effect of modified cream form of Sahachara Ghrita on Mukhdushika with special reference to Acne vulgaris.

Materials and Methods: Sahachara Ghrita will be prepared as per classical reference. Modified cream form Sahachara Ghrita will be prepared as per texts. The prepared formulation will be assessed with organoleptic characters and physicochemical parameters. Clinical study will be carried out in 2 groups with modified cream form of Sahachara Ghrita and standard drug Shalmali Kantakadi Lepa respectively. They will be evaluated for their results on Mukhadushika.

Result: The analytical parameters will be assessed to establish pharmaceutical standardization. The result of clinical study will be drawn from the mentioned assessment criteria. Statistical analysis will be done accordingly.

Conclusion: If significant positive results are obtained in this work, then it will be a valuable contribution and evidence that the drug modified cream form Sahachara Ghrita is effective in Mukhadushika.

Keywords: Mukhadushika, Acne vulgaris, Sahachara Ghrita, Modified cream.

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Introduction

Mukhadushika is one of the most prevalent skin diseases. *Mukhadushika* is categorized as one of the types of "Kshudraroga".[4] *Mukhadushika* commonly manifests during the puberty stage, that's why it's also termed as *Yauvanpidika*[5] or *Tarunyapitika*.

In modern science, it can be correlate with Acne vulgaris. *Mukhadushika* is a disorder in which papules resemble into *Shalmali* thorn-like lesions on the face due to vitiated *Khapa*, *Vata Dosha*, and *Rakta Dhatu*. [6,7]

Samanya Hetu

1. Kalaja - Yuva-Avastha (Young age)
2. Aharaja
 - A. Excess consumption of *Katu*, *Tikta*, *Amla*, *Lavana Rasa*
 - B. *Snigdha*, *Ushna*, *Tikshna Ahar*.
3. Viharaja - Atapasevana.
4. *Manasika* - *Atikrodha*, *Atichinta*, *Atibhaya*, *Svabhava*.

Samprapti

Hetu Sevana

↓

Vata and Kapha Dosh Prakop

Rakta Dushti

↓

Vishamata in Rasa-Rakta Dhatvagni.

↓

Meda Sanga in Romakupa of Mukhapradesh

↓

Mukhadushika

Samprapti Ghatak

1. Dosha - Vata & Kapha
2. Dhatu - Rakta
3. Agni - *Vishamata in Rasa-Rakta Dhatvagni*
4. Srotas - *Raktvaha* (mainly),
5. Srotodusti Prakara - *Sanga*.
6. Adhithana - *Mukhapradesh*
7. *Sthana Samshraya* - *Medogranthi* of *Mukhapradesh*
8. *Roga Marga* - *Bahyantara*
9. *Pratyatmakal Lakshana* - *Shalmali Kantaka* like *Pidika*

(A cone-shaped eruption on the face, similar to *Shalmali Kantaka* is known as *Mukhadushika*)

There is considerable scope for additional clinical trials from both modern dermatological and Ayurvedic perspectives to deepen our understanding of *Mukhdushika* and its management.

For *Mukhadushika*, treatment is as described:

1. *Nidanparivarjan*
2. *Shodhan Chikitsa*
3. *Shaman Chikitsa*

- A. *Antahparimarjan Chikitsa* (internal medication)
- B. *Bahirparimarjan Chikitsa* (Topical applications)

E.g. *Abhyanga* (oil or *Ghrita* massage) e.g. *Sahachara Ghrita* (intervention)[2]

Lepas e.g. *Shalmali Kantak Lepa*[8,9] (control group)

Need of study

In Ayurveda, *Sahachara Ghrita* is mentioned in *Bhaishajyaratnavali* for *Mukhadushika*. Studying the modified cream form of *Sahachara Ghrita* validates its traditional usage and promotes its integration into treatment modalities for acne. To address the challenges of applying *Sahachara Ghrita*, a cream formulation is being developed for easier and more convenient application.

Creams

Creams are semi-solid or viscous liquid emulsions, either of water-in-oil or oil-in-water type, whose consistency varies according to proportions of water and oil. Modified cream form of *Sahachara Ghrita* is categorized in Water in oil (w/o) type of cream.

Nature of the knowledge gap identified

Table 1: Nature of the knowledge gap identified

Research Gap Types	Type of research gap used
Knowledge Gap	There is no previous work done on effectiveness of modified cream form of <i>Sahachara Ghrita</i> on <i>Mukhadushika</i> .
Methodological Gap	After extensive literature search, the research scholar could not find any clinical study of modified cream form of <i>Sahachara Ghrita</i>
Practical knowledge Gap	There are conflicting results regarding the pharmaceutical and analytical observations of the stated drugs.
Empirical knowledge gap	The insufficient literature regarding conceptual, pharmaceutical, analytical and clinical studies has formed an empirical knowledge gap.

Aim and Objectives

Aim: To evaluate the Pharmaceutico-Analytical study and clinical effect of modified cream form of *Sahachara Ghrita* on *Mukhdushika* with special reference to Acne vulgaris.

Objectives

Primary objectives

1. To prepare *Sahachara Ghrita* and its cream.
2. To analyse organoleptic & physico-chemical para. of *Sahachara Ghrita*, its modified cream form.
3. To compare the effect of modified cream form *Sahachara Ghrita* and *Shalmali Kantakadi Lepa*.

Materials and Methods

Present work will be conducted under foll. headings.

1.1 Pharmaceutical Study: In this study, *Sahachara Ghrita* will be prepared as per classical reference to establish pharmaceutical standardization. This pharmaceutical study will be done according to the following steps.

- A) Selection of Raw material
- B) Procurement of raw drugs - All raw drugs will be collected/procured from the field and authentic reliable sources.
- C) Authentication of raw material - All raw materials will be verified and authenticated.

A) Pharmaceutical:

1. Sahachara Ghrita: It contain foll. ingredients

Sneha Draya: Goghrita[10-12]

Kwatha Dravya

Table 2: Kwatha Dravya

SN	Ingredient	Botanical Name	Part Used
1.	Sahachara[13-15]	Barleria prionitis	Panchang
2.	Shirisha [16-19]	Albizia lebbeck	Twak
3.	Dashmoola[20]		
a.	Bilva [21,22]	Aegles marmelos	root
b.	Agnimanth[23]	Premna serratifolia	Root
c.	Syonak[24]	Oroxylum indicum	Root
d.	Kashmari[25]	Gmelina arborea	Root
e.	Patla [26]	Stereospermum suaveolens	Root
f.	Bruhati[27]	Solanum indicum	Root
g.	Kantakari [28]	Solanum surattense	Root
h.	Gokshur[29]	Tribulus terrestris	Root
i.	Shaliparni[30]	Desmodium gangeticum	Root
j.	Prushniparni	Uraria picta	Root

Kalka Dravya

Table 3: Kalka Dravya

SN	Ingredient	Botanical Name	Part Used
1.	Pippali [31]	Piper longum	Fruits
2.	Pippalimul [32]	Piper longum	Root
3.	Chavya [33]	Piper retrofractum	Roots, Fruit
4.	Chitrakmul [34]	Plumbago zeylanica	Root
5.	Sunthi [35]	Zinziber officinale	Rhizome
6.	Vidang [36]	Embelia ribes	Fruit
7.	Saindhav [37]	SodiI chloridum	
8.	Sauvarchalavan [38]	Sodii muras	
9.	Samudralavan [39]		
10.	Bidlavan [40]	Sal nigrum indicum	
11.	Tankan [41]	Borax or Bicarbonate of soda	
12.	Swarjik Kshar [42]	Caroxylones botidum	
13.	Yavakshar[43]	Hordeum vulgare	
14.	Vrishchikali [44]	Tragia involucrata	
15.	Sindur	Red oxide of mercury	
16.	Gairik [45]	Ochre	

Abhav Pratinidhi Dravya[46]

In present reference for *Sahachara Ghrita*, *Audbhida Lavan* is an ingredient. But it is not available.

When any *Lavana* is not available, *Saidhava* is used at its place. [47]

Preparation of Sahachara Ghrita

- Collection of raw material.
- Ghrita Murcchana* will be carried out according to the texts.
- Sahachara Panchanga*, *Dashamoola*, and *Shirisha Tvak* will be coarsely powdered separately and soaked overnight in separate vessels. The next morning, each drug will be boiled separately over *Mandagni* until one-fourth of the original quantity remains, and then filtered through a clean cotton cloth.
- All the ingredients mentioned in *Kalka Dravya* [from *Pippali* to *Gairik*] will be crushed into a fine powder and mixed with water to make a *Kalka*.
- Go-ghrita* will be taken in a vessel and heated slightly over *Mandagni*. Then, the *Kalka* and above three *Kwathas* will be added subsequently to the *Ghrita* and heated to prepare *Paka* until the *Sneha Siddha Lakshanas* are attained. Afterward, the vessel will be taken out from the fire, and the *Ghrita* will be filtered.

- Finally, it will be stored in steel containers.

Preparation of cream

Table 4: Content of cream

SN	Excipients	Category
1.	Bees wax	Base
2.	Liquid paraffin	Emollient
3.	Borax	Emulsifying agent
4.	Methyl paraben	Preservatives
5.	Distilled water	
6.	Sahachara Ghrita	

Method of preparation of cream

1. Oil phase

A) Liquid paraffin and beeswax will be added into one beaker, and the mixture will be heated.

B) *Sahachara Ghrita* will then be added to the oil phase beaker.

2. Aqueous phase

C) Borax will be taken and dissolved in distilled water in another beaker [aqueous phase].

D) The aqueous phase will be slowly added to the oil phase.

E) The mixture will be stirred vigorously until it forms a smooth cream.

F) A preservative will be added.

G) The cream will then be poured into a container.

2. *Shalmali Kantakadi Lepa*[8]

A) The *Shalmali Kantak* will be collected.

B) The drug will be cleaned and dried.

C) They will be powered by pounding with a mortar and pestle.

B) Analytical study

Analytical study of *Sahachara Ghrita*

Organoleptic Characters

- Shabda* [Sound]
- Sparsh* [Sensation]
- Rupa* [Colour]
- Rasa* [Taste]
- Gandha* [Odor]

Objective parameters of the *Sahachara Ghrita*

Physico-Chemical Parameters

- Refractive index
- Specific gravity

- Acid value
- Saponification value
- Iodine value
- Peroxide value

Analytical study of modified cream form of *Sahachara Ghrita*

Physico-chemical parameter of modified cream form of *Sahachara Ghrita*

- pH
- Viscosity
- Acid value
- Specific gravity
- Spread ability
- Rancidity

Organoleptic Characters of modified cream form of *Sahachara Ghrita*

- Shabda*
- Sparsha*
- Rupa*
- Rasa*
- Gandha*

C) Experimental Study

- Assessment for eligibility.
- Randomization.
- Allotment of trial Group A and trial Group B.
- Trial Group - A will receive modified cream form of *Sahachara Ghrita* and Trial Group - B will receive *Shalmali Kantak Lepa*
- Intervention for 30 days.
- Individual follow-up of trial group A and B will be done 0 th, 15th, 30th and 45th day.
- Final analysis after completion of trial.
- Conclusion and Result.

Inclusion criteria

- Age group 18-30 years irrespective of gender.
- Patient having symptom of *Mukhadushika*
 - Shalmali Kantak* like eruptions.
 - Saruja Pidika* (painful acne)
 - Ghana Pidikas* (hard and thick acne)
 - Medogarbha Pidikas* (acne filled with oil/sebum/pus)

Shotha (Inflammation)

3. Patient having symptom of acne vulgaris

- Open comedones (White head)
- Close comedones (black heads)
- Papule
- Pustule.

Exclusion criteria

1. Patient suffering from any other skin disease and any allergic condition.
2. Patients of severe acne having inflammatory cyst.
3. Patients having hormonal imbalance like PCOD etc.
4. Genetic disorders

Withdrawal criteria

1. Patient willing to discontinue trial.
2. If patient develops any allergy due to study drug.
3. Inter current illness.

Sample size

Sample size in present study will be 30 for each group thus total 60 will be estimated sample size for this study.

Table 5: Sample Size

	Group – A	Group – B
No. of patients	30	30
Drug	Modified cream form of Sahachara Ghrita	Shalmali Kantak Lepa
Dose	Quantity sufficient	Quantity sufficient
Route of Administration	Local application (face)	Local application (face)
Intervention	30 days	30 days
Duration of study	45 days	45 days
Follow-up	0th, 15th, 30th & 45th days.	0th, 15th, 30th & 45th days.

Subjective Criteria

Table 6: Subjective Criteria

SN	Symptoms	0th day	15th day	30th day	45th day
1.	Saruja (pain) Pidika				
2.	Pidika with Shotha				
3.	Ghana Pidika				

Objective Criteria

Table 7: Objective Criteria

SN	Parameter	0th day	15th day	30th day	45th day
1.	No. of Pidika				
2.	Medogarbha Pidikas (acne filled with oil/sebum/pus)				
3.	Open comedones (White head)				
4.	Close comedones (black heads)				
5.	Papule				
6.	Pustule				
7.	Nodules				
8.	Scarring				

Grading scale

Table 8: No. of Pidika

SN	No. of Pidikas	Grade
1.	No Pidika	0
2.	1-5 Pidikas	1
3.	5-10 Pidikas	2
4.	10-15 Pidikas	3
5.	More than 15 Pidika	4

Table 9: Medogarbha

SN	Medogarbha	Grade
1.	No Pidaka containing fat inside	0
2.	1- 5 Pidaka containing fat inside	1
3.	5- 10 Pidaka containing fat inside	2
4.	10 - 15 Pidaka containing fat inside	3
5.	More than 15 Pidaka containing fat inside	4

Table 10: Closed comedones

SN	Closed comedones (white heads)	Grade
1.	No Closed comedones in area	0
2.	1- 5 Closed comedones in area	1
3.	5- 10 Closed comedones in area	2
4.	10- 15 Closed comedones in area	3
5.	More than 15 Closed comedones in area	4

Table 11: Open comedones

SN	Open comedones (black heads)	Grade
1.	No open comedones in area	0
2.	1- 5 open comedones in area	1
3.	5- 10 open comedones in area	2
4.	10- 15 open comedones in area	3
5.	More than 15 open comedones in area	4

Table 12: Papules

SN	Papules	Grade
1.	No papules in area	0
2.	1- 5 papules in area	1
3.	5- 10 papules in area	2
4.	10- 15 papules in area	3
5.	More than 15 papules in area	4

Table 13: Pustules

SN	Pustules	Grade
1.	No Pustules in area	0
2.	1- 5 Pustules in area	1
3.	5- 10 Pustules in area	2
4.	10- 15 Pustules in area	3
5.	More than Pustules in area	4

Table 14: Nodules

SN	Nodules	Grade
1.	No Nodules in area	0
2.	1- 5 Nodules in area	1
3.	5- 10 Nodules in area	2
4.	10- 15 Nodules in area	3
5.	More than Nodules in area	4

Investigator's Global Assessment [IGA] of acne severity

Table 15: Investigator's Global Assessment (IGA) of acne severity

0	Clear	Erythema may be present
1	Almost clear	A few scattered comedones and a few small papules
2	Mild	Easily recognisable; less than half the face is involved. Some comedones and some papules and pustules
3	Moderate	More than half the face is involved. Many comedones, papules and pustules. One nodule may be present
4	Severe	Entire face is involved, covered with comedones, numerous papules and pustules, and few nodules and cysts

Criteria for assessment

Table 16: Criteria for assessment

Unchanged	0 to 25% improvement
Mild	26 to 50% improvement
Moderate	51 to 75% improvement
Marked	76 to 100% improvement

Statistical analysis

Data will be coded and analysed with the statistical software, STATA, version 10.1 (2011) by StataCorp, Texas, USA.

Methods

1. Study design: Pharmaceutical, Analytical, Experimental
2. Study period: 18 months study
3. Study centers: Present work will be conducted at the following study centres.

A) Pharmaceutical work will be carried out at the department of *Rasashastra & Bhaishajya Kalpana* of our Institute.

B) Analytical work will be carried out at certified Analytical laboratory.

C) A Clinical study will be carried out in the OPD of the Study centre.

D) We will approach other institutes as per need of study.

Statistical analysis:

1. Results will be expressed in mean value and standard error of the mean
2. Statistical analysis will be applied accordingly.

Observations and Results

Stepwise observations will be recorded and presented in the form of tables, charts and pictures, etc.

Discussion

Mukhadushika / Acne vulgaris is a common chronic inflammatory condition of the skin. It is a prevalent issue affecting approximately 80% of teenagers and young adults.

Acne can lead to significant psychological impact, so there is a need to find efficient treatments that can improve patient quality of life.

Ayurveda offers a reliable and efficient alternative for treating acne vulgaris.

Traditional medicine validation: *Sahachara Ghrita* is mentioned in *Bhaishajya Ratnavali* for *Mukhadushika*. Studying the modified cream form of *Sahachara Ghrita* validates its traditional usage and promotes its integration into treatment modalities for acne.

Treatment efficacy: Understanding the effectiveness of modified cream form of *Sahachara Ghrita* can offer valuable insight into its potential as a treatment option To address the challenges of applying *Sahachara Ghrita*,

A cream formulation is being developed for easier and more convenient application.

Conclusion

The present study is planned to study the advancement of *Ghrita* form into cream. This a genuine attempt to fill the gap of few scientific evidences available and if significant positive results are obtained then it will be a valuable contribution and evidence that modified cream form of *Sahachara Ghrita* are as effective as in *Mukhadushika*.

Scope of study:

- The positive outcome of the study will give the evidence that the *Modified cream form of Sahachara Ghrita* is more effective than *Shalmali Kantak Lepa*.
- Possibility of other outcome *Shalmali Kantak Lepa* is more effective than Modified cream form of *Sahachara Ghrita*.
- The difference in the outcome with reference to both the drugs will offer a light on the effectiveness of Modified cream form of *Sahachara Ghrita* in *Mukhadushika*.
- If the *Shalmali Kantak Lepa* is more effective, then *Shalmali Kantak Lepa* will remain in practice.
- With the positive outcome of Modified cream form of *Sahachara Ghrita*, further clinical studies can be conducted on a larger population.

Consent: Consent form will be signed from the subjects before start of study.

Ethical approval: Ethical approval will be taken from the Institutional Ethical Committee at our Institute.

Competing Interests: No competing interests exist.

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