



Research Article

A SINGLE CENTRE OPEN LABEL NON-RANDOMIZED PHASE-IV POST MARKETING SURVEILLANCE STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ROOP MANTRA AYURVEDIC MEDICINAL CREAM

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ABSTRACT
Objectives: The objective of the study was to evaluate the efficacy and safety of a polyherbal Roop Mantra Ayurvedic Medicinal Cream in subjects with acne, facial scars, pimples, blemishes, dull and dry skin. **Methods:** This was a 60-day, single-centre, open-labelled, non-randomized phase-IV surveillance study with 120 subjects. Subjects were selected based on the study's inclusion criteria. The study included three scheduled clinical visits on days 0 (screening and baseline visit), 30 (follow-up visit), and 60 (final visit). Following an evaluation of baseline data, all subjects were given Roop Mantra Ayurvedic Medicinal Cream for 60 days. The primary outcome of the study was to assess the efficacy of Roop Mantra Ayurvedic Medicinal Cream based on changes in parameters such as skin texture, skin health, global acne assessment parameters and an investigator assessment scale. The secondary outcome of the study was the determination of local intolerance and adverse effects to Roop Mantra Ayurvedic Medicinal Cream. **Results:** The study findings revealed that the use of Roop Mantra Ayurvedic Medicinal Cream for 60 days improved skin texture and appearance while significantly reducing acne, pimples, blemishes, and skin dryness. Roop Mantra Ayurvedic Medicinal Cream was likewise dermatologically well tolerated and did not cause any adverse effects during the study period. **Conclusion:** Roop Mantra Ayurvedic Medicinal Cream showed highly satisfactory results in terms of skin texture, skin appearance and general acne parameters without having any adverse effects on the skin. Given the positive outcomes, Roop Mantra Ayurvedic Medicinal Cream is clinically effective and safe alternative for treating various skin problems.

INTRODUCTION

The skin is the most exterior protective barrier of the human body and it is continuously exposed to environmental stimuli such as microorganisms, UV radiation, fluctuating temperatures, chemicals and air pollutants.^[1] Chronic exposure to various environmental stimuli affects the morphological and biophysical characteristics of the skin, resulting in skin dryness, roughness, scaling, rashes, and fungal and bacterial infections.^[2, 3] Furthermore, several intrinsic

factors, such as genetics, ageing and endogenous hormones, are direct contributors to these manifestations.^[2] Therefore, long-term maintenance of a healthy appearance of skin has been one of the most difficult challenges in the cosmetic industry.^[4] Certain skin care approaches for preserving skin well-being include gentle washing, proper hydration and moisturization of the skin, and protection from irritants and bright sunlight.^[5]

People are paying great attention to the healthy appearance of their skin by maintaining skin integrity and well-being. With increased awareness of environmental damage, traditionally used medicinal plants are gaining popularity and acceptability among cosmetic manufacturers and consumers for the treatment of various skin disorders due to their excellent therapeutic potential with no or minimal side

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effects compared to synthetic drugs.^[6] With the technological advancements in the beauty sciences, therapeutically essential age-old herbs are being used to develop skin-friendly, effective, and safe topical formulations and cosmetics for a variety of skin disorders.^[7] Plants contain a diverse array of phytochemicals with numerous therapeutic potentials, including anti-aging, antioxidant, anti-inflammatory, rejuvenating, restorative, antiseptic, and antimicrobial properties that result in a calm or smooth skin appearance, as well as restoring, healing, and protecting the skin.^[8] Several herbs and flora are used in ayurvedic cosmetics for beautification and restoring normal skin appearance by maintaining normal skin functions, delivering vital nutrients to the skin, and avoiding adverse effects of external stimuli on the body.^[9] Many medicinal plants, including *Aloe barbadensis*, *Ocimum sanctum*, *Curcuma longa*, *Glycyrrhiza glabra*, *Vitis vinifera*, *Azadirachta indica*, and others, are used in ayurvedic cosmetic formulations.^[10]

In this perspective, Roop Mantra Ayurvedic Medicinal Cream, a poly-herb formulation, has been developed and is being promoted in India for the treatment of acne, facial scars, blackheads, blemishes, dull and dry skin. The formulation is made up of 12 medicinal herbs that have been chosen for their traditional usage as well as scientific rationale for modern use. Individually, these plants are widely described in the literature for their potential cosmetic benefits. The current post-marketing surveillance study sought to evaluate adverse effects, efficacy, and other important parameters associated with the use of Roop Mantra Ayurvedic Medicinal Cream in subjects suffering from acne, facial scars, blackheads, blemishes, dull, and dry skin.

MATERIALS AND METHODS

Study Population and Enrolment

The study subjects were recruited through the outpatient clinic and the dermatologist at the study centre identified eligible participants. Potential subjects were invited to participate in this study. The study included 120 subjects. Prior to participation in the study all study subjects signed an informed consent form.

Subject Selection Criteria

Inclusion Criteria

Patient’s inclusion criteria were male or female, aged 18–45, who voluntarily signed consent form after being well informed about the aim of this program. The skin type of the participants had acne, facial scars, blackheads, blemishes, dull and dry skin and one person who was motivated and willing to participate and attend all scheduled visits was included in this study.

Exclusion Criteria

Participants with a history of skin allergy to an external or internal factor, participants with any type of surgery or ocular disorder, pregnant or breast-feeding women, and participants who had participated in another cosmetic clinical trial were excluded. Participants who had used face bleach, facial scrub, hair removal, or any other product within 2 weeks of screening were also excluded from this study.

Study Interventions

The study intervention, Roop Mantra Ayurvedic Medicinal Cream (Fig 1), was manufactured and provided by Divisa Herbal Care., Chandigarh, India. The study kit contains Roop Mantra Ayurvedic Medicinal Cream for 60 days, which was given to all participants. The cream contained extracts of *A. barbadensis*, *O. sanctum*, *C. longa*, *Cucumis sativus*, *Daucus carota*, *V. vinifera*, *G. glabra*, *Citrus limon*, *Pyrus malus*, and oils of *Santalum album*, *A. indica*, and *Prunus amygdalus*. Subjects were instructed to apply a small amount of this cream using their finger tips and massage gently over cleansed faces twice a day (morning and evening).



Fig. 1 The study product (Roop Mantra Ayurvedic Medicinal Cream)

Study Design

The current study was a non-randomized, open-label, single-arm, single-centric, phase IV post-marketing surveillance study. The study was conducted at Akshatha Skin and Hair Care Centre (Bangalore, India) between November 2019 and February 2021 under strict compliance with the ICMR, ICH-GCP and Declaration of Helsinki guidelines. The total study duration was 60 days, including three scheduled clinical visits on days 0 (screening and baseline visit), 30 (follow-up visit), and 60 (final visit). As part of the informed consent process, the principal investigator and/or a team member of the study explained the study details to the subjects. All participants were assessed for physical examinations,

vital signs, demographic data, and medical/surgical history. After receiving informed consent, subjects were evaluated for eligibility based on inclusion and exclusion criteria. Eligible subjects were evaluated for pregnancy and for any allergies to external or internal factors. All eligible participants were instructed to document adverse events and the daily use of the study intervention (date and time) throughout the study period. The study intervention (Roop Mantra Ayurvedic Medicinal Cream) was assigned to all subjects for a period of 60 days.

Outcome Measures

Primary Outcomes

The primary outcome of the study was to assess the efficacy of Roop Mantra Ayurvedic Medicinal Cream in male and female subjects suffering from acne, pimples, blemishes, dullness, and dry skin. Primary outcomes included changes in skin

characteristics, the Global Acne Assessment (GAA) score, and skin appearance at the end of the study.

Skin characteristics

Skin characteristics were assessed by administering a self-assessment questionnaire to the participants on days 30 and 60. Participants were scored on their skin characteristics as follows: 1 = dry, 2 = normal, 3 = combination, and 4 = oily skin types.

GAA Score

Using the GAA chart, a dermatologist rated the severity of acne, pimples, and blemishes on days 0 and 60. The difference between the mean GAA score at days 0 and 60 was assessed. The severity of acne, pimples, and blemishes were scored and graded on a 6-point scale (Table 1). A lower GAA score indicates a reduction in the severity of acne, blackheads, and blemishes.

Table 1: GAA grading and scoring system

Grade	Score	Definition
Clear	0	There may be residual hyperpigmentation and erythema.
Almost clear	1	A few scattered comedones and a few (less than five) small papules.
Mild	2	Easily recognizable; less than half of the face is involved. Many comedones and many papules and pustules are present.
Moderate	3	More than half of the face is involved. Numerous comedones, papules, and pustules.
Severe	4	The entire face is affected and covered with comedones, numerous papules and pustules, and few nodules and cysts.
Very Severe	5	Highly inflammatory acne covering the face; nodules and cysts are present.

Skin Appearance

A self-assessment questionnaire (SAQ) designed according to investigator assessment parameters, including skin quality, acne and blemishes, scarring, lightness, and skin enhancement, was used to assess change in the appearance of the skin from day 30 to day 60. SAQ scores on a 5-point scale were used to rank each skin parameter, with change = 1, fair = 2, good = 3, very good = 4, and excellent = 5. A higher SAQ score indicates an improvement in the appearance of the skin.

Secondary Outcomes

The safety and tolerability of the study intervention were assessed at days 15 and 30 using a dermatologist's physical assessment and self-reported adverse events by participants such as erythema, dryness, oedema, urticaria, allergic reactions, and others.

Ethical Approval

This study protocol was approved by the ACE Independent Ethics Committee with Protocol No: SBS/DIV/002/2020 and was registered with the Clinical Trials Registry - India (CTRI/2020/11/029427) on November 27, 2020.

Statistical Analysis

Demographic characteristics and results of the study were summarised with descriptive statistics including average, standard deviation (SD), frequency and percentages. Changes in the mean GAA and SAQ scores from day 30 to day 60 were assessed by paired t-test. Statistical analysis was carried out using SPSS statistical software version 23.0 (SPSS Inc., USA). The P value, 0.05, was considered statistically significant.

RESULTS

Subjects Flow and Baseline Characteristics

A total of 120 subjects were screened and recruited for this study, with 45 (37.5%) men and 75 (62.5%) females having a mean age of 29.78±7.83 years. During the study period, none of the individuals dropped out. Fig. 2 depicts the flow of participants.

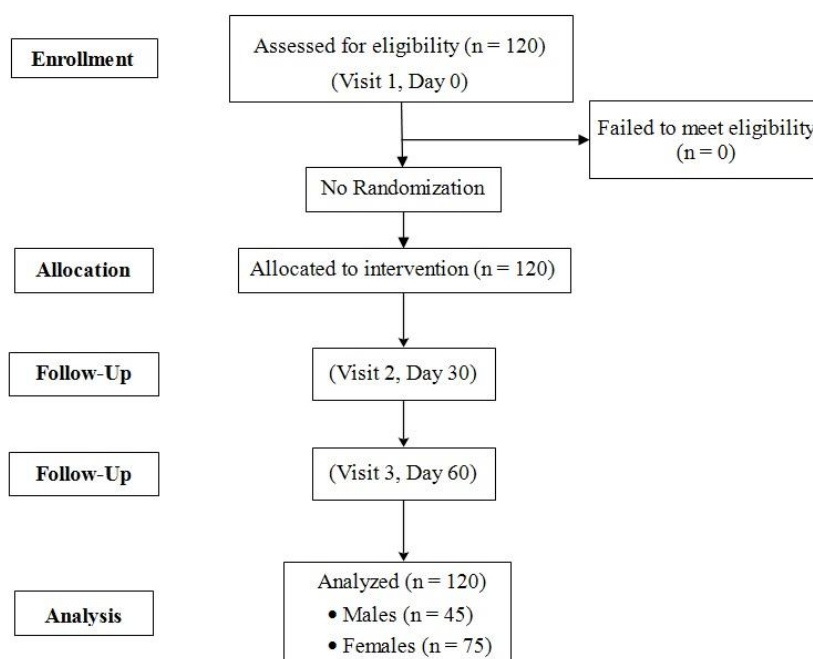


Fig. 2 Study flow chart

Skin Characteristics

Table 2 provides an overview of self-reported skin characteristics at days 30 and 60. On day 30, participants' skin types were reported as oily 15.83%, combination 26.67%, dry 22.50%, and normal 25.0%. After using Roop Mantra Ayurvedic Medicinal Cream, skin characteristics changed to oily 4.17%, combination 5.0%, dry 10.83%, and normal 78.33%. At the end of the study, 75 of the 120 participants were found to have healthy, normal skin.

Table 2: Frequency of skin characteristics at days 30 and 60

Skin Characteristics	Visit 2, Day 15 (n=120)		Visit 3, Day 30 (n=120)	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
Oily	19	15.83	5	4.17
Combination	32	26.67	6	5.0
Dry	27	22.50	15	10.83
Normal	30	25.0	94	78.33

Global Acne Assessment (GAA)

In this study, 71 (59.17%) of the participants had acne, blemishes, or pimples. When compared to day 0, the frequency and severity of acne, blemishes, and pimples were significantly reduced on day 60 (Table 3). On day 60, 61.97% of subjects had clear skin, while 26.76% had nearly clear skin, compared to 8.49% and 2.81 on day 0 respectively. In addition, the mean GAA score significantly decreased from 2.44 ± 0.65 (at day 0) to 0.52 ± 0.81 (at day 60). The reduction in GAA score was statistically significant [p<0.0001; mean difference, 1.797; 95% CI, 1.65 to 1.95] (Fig. 3).

Table 3: Frequency of acne, blemishes, and pimples severity at different visits

Symptom severity	Visit 1, Day 0 (n=71)		Visit 3, Day 60 (n=71)	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
Clear	6	8.45	44	61.97
Almost clear	2	2.81	19	26.76
Mild	37	52.11	2	2.81
Moderate	21	29.57	5	7.04
Severe	5	7.04	1	1.40
Very severe	0	0	0	0

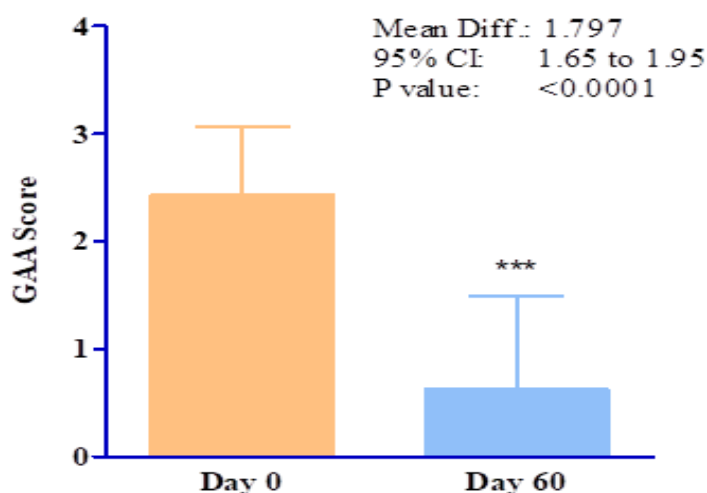


Fig. 3 Mean change in GAA score from day 0 (Visit 1) to day 60 (Visit 3)

Assessment of Skin Appearance

The study's findings revealed that after using Roop Mantra Ayurvedic Medicinal Cream for 60 days, 69.17% of subjects reported excellent skin appearance, and 15.83% reported very good skin appearance, compared to 20.0% and 18.33% on day 30 (Table 4). Results of SAQ scores on skin appearance parameters, including skin quality, acne and blemishes, scars, skin radiance, and skin improvement, are summarized in Table 5. Table 3 shows that SAQ scores for all skin appearance parameters were significantly ($p < 0.0001$) higher at day 60 than at day 30.

Table 4: Frequency of different skin appearances at different visits

Symptom severity	Day 30 (n=120)		Day 60 (n=120)	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
Change	19	15.83	3	2.50
Fair	25	20.83	7	5.83
Good	30	25.0	8	6.67
Very good	22	18.33	19	15.83
Excellent	24	20.0	83	69.17

Table 5: Mean change in SAQ scores from day 30 to day 60

Assessment	Day 30	Day 60	Mean diff.	95% CI	p value
	SAQ Score (Mean \pm SD)	SAQ Score (Mean \pm SD)			
Skin quality (n=120)	3.06 \pm 1.36	4.43 \pm 1.02	-1.38	-1.59 to -1.16	< 0.0001
Acne and blemishes (n=75)	2.27 \pm 1.03	4.08 \pm 0.93	-1.81	-2.06 to -1.57	< 0.0001
Scars (n=15)	1.73 \pm 0.70	3.47 \pm 0.92	-1.73	-2.22 to -1.24	< 0.0001
Skin radiance (n=120)	2.83 \pm 1.12	4.43 \pm 0.98	-1.59	-1.78 to -1.40	< 0.0001
Skin improvement (n=120)	3.06 \pm 1.36	4.43 \pm 1.02	-1.38	-1.59 to -1.16	< 0.0001

Assessment of Safety

A questionnaire was used to assess local tolerance of the Roop Mantra Ayurvedic Medicinal Cream on days 30 (visit 2) and 60 (visit 3) for the occurrence of erythema, dryness, oedema, urticaria, allergic responses, and any other adverse effects. The subjects reported no local intolerance to the study product during the study period (Table 6). None of the study participants experienced adverse reactions such as stinging, itching, or burning after using the product during the 60-day study period.

Table 6: Adverse effects reported to the study intervention

Adverse effects	Day 30 (n=120)	Day 60 (n=120)
Erythema	0/120	0/120
Dryness	0/120	0/120
Oedema	0/120	0/120
Urticaria	0/120	0/120
Allergic reactions	0/120	0/120
Any others	0/120	0/120

DISCUSSION

Herbal extracts derived from traditional medicinal plants are well known to improve various skin disorders.^[11] Currently, different herbal extracts are being used in dermo-cosmetics for the long-term treatment of various skin disorders. Use of herbal Medicinal Cream can improve the texture of damaged skin by improving skin elasticity, blood circulation, hydration, skin barrier functions, regulating sebum production, and by inhibiting melanin synthesis, free radical damage, and the growth of microorganisms on the skin.^[8, 12-15]

In this context, Roop Mantra Ayurvedic Medicinal Cream contains 12 medicinal plants, which have a wide variety of cosmeceutical applications. *A. barbadensis* promotes wound healing, skin hydration, increases the flexibility and reduces the fragility of the skin.^[16, 17] *O. sanctum* prevents wrinkle formation, oxidative damage, inflammation, and bacterial infections.^[18, 19] *C. longa* plays an important role in the treatment of a variety of dermatologic diseases due to its wound healing, anti-aging, anti-inflammatory, antimicrobial, and antioxidant properties.^[20]

C. sativus rejuvenates skin due to its cooling, hydrating, anti-ageing, antioxidant, and anti-inflammatory properties.^[21, 22] *D. carota* has strong antioxidant, antifungal, and antibacterial properties.^[23] *V. vinifera* improves and maintains the skin's natural barrier, hydration, protects the skin from oxidative damage, and soothes skin inflammation.^[24, 25] *G. glabra* is used in cosmetic formulations as a depigmenting agent to inhibit the tyrosinase enzyme.^[26] *C. limon* fruit extract is frequently used in various cosmetic preparations due to its anti-ageing, antioxidant, and depigmenting properties.^[27] Apples are enriched with polyphenols which have radioprotective and hydroxyl free radical scavenging activities.^[28] Apple extract is also thought to be beneficial in reducing sebum production, decreasing melanin levels, greasiness, and erythema caused by acne, and improving the appearance of oily facial skin.^[29] *S. album* oil has promising therapeutic effects in the treatment of various skin disorders such as acne, psoriasis, eczema, common warts, and molluscum contagiosum.^[30] *A. indica* oil has strong antibacterial, antifungal, and anti-inflammatory properties.^[31] *P. amygdalus* is beneficial

in the treatment of skin dryness and trans-epidermal water loss.^[32] In this study, the Roop Mantra Ayurvedic Medicinal Cream was found to have excellent efficacy in improving skin texture and skin appearance, as well as reducing acne, blemishes, and pimples after 60 days. The effectiveness of Roop Mantra Ayurvedic Medicinal Cream in the improvement and reduction of skin texture, skin appearance, and global acne parameters (acne, blemishes, and pimples) can be due to the synergistic therapeutic effects of the ingredients, including anti-ageing, antioxidant, anti-inflammatory and antimicrobial properties.

The use of skin or cosmetic products may occasionally result in localised unpleasant effects such as allergic reactions, erythema, photoreaction, irritation, and other undesirable events. Therefore, safety evaluation of skin products is necessary to establish the inherent risks of the substances present in the cosmetics. Although the negative effects of skin or cosmetic products may vary on an individual basis.^[33] In this study, we evaluated the skin safety of the Roop Mantra Ayurvedic Medicinal Cream in 120 subjects. The results of the study indicated that application of Roop Mantra Ayurvedic Medicinal Cream for up to 60 days produced no dermatological adverse effects or local intolerance to the study cream.

CONCLUSION

A 60-day non-randomized post-marketing surveillance study was conducted to evaluate the efficacy and safety of Roop Mantra Ayurvedic Medicinal Cream in reducing acne, pimples, blemishes, dullness, and dryness. The product was shown to be effective in eliminating all of the above skin concerns without causing any side effects. Overall, the present study found that the Roop Mantra Ayurvedic Medicinal Cream is clinically effective and safe for human use.

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