

EVALUATION OF SAFETY AND EFFICACY OF POLYHERBAL FAIRNESS CREAM

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ABSTRACT

Fair skin has always been the desire of people since ages and has been associated with beauty. Earlier, most of the people used homemade (turmeric, milk, honey) products and lotions to make their skin lighter in shade. With the assumption of fair skin as a sign of beauty, there has been bias for the skin colour in most of the countries. People use fairness cream to improve their complexion, irrespective of whether they have dark or fair complexion. The purpose of this open prospective, non-comparative Phase III clinical trial was to evaluate the safety and efficacy of Polyherbal Fairness Cream as a result of repeated application for 4 weeks. Fifty subjects were included in this study. They were advised to apply fairness cream twice daily for a period of 30 days. All the patients were followed-up at weekly intervals for a period of 4 weeks. Response to Fairness Cream was evaluated on a 5-point visual analogue scale. All subjects completed the study and significant reduction in dark complexion, increase in skin softness, and skin glowing effect was seen at the end of the study. There were no adverse effects reported during the study and compliance to the use of formulation was excellent.

KEYWORDS: Polyherbal Fairness Cream, Skin complexion, Skin glowing effect, Moisturizing effect.

INTRODUCTION

Fair skin has always been the desire of people since ages and has been associated with beauty. Earlier, most of the people used homemade (turmeric, milk, honey) products and lotions to make their skin lighter in shade. With the assumption of fair skin as a sign of beauty, there has been bias for the skin colour in most of the countries. People use fairness cream to improve their complexion, irrespective of whether they have dark or fair complexion. We are introducing Polyherbal fairness cream with their safety and efficacy report.

Skin has many vital functions i.e. thermoregulation, protection, metabolic functions and sensation. The skin is divided into two main regions, the epidermis, and the dermis.¹ Melanin is primary determinant of human skin colour. Melanin is produced in specialized skin cells called melanocytes that are located in the epidermis.² The increased production of melanin in human skin is called melanogenesis.³ It is stimulated by DNA damage caused by UVB-radiation, and leads to a delayed development of tan.⁴ In humans, the two types of melanin⁵ present in the skin (eumelanin and pheomelanin) are responsible for different skin tones (which is induced by ultraviolet radiation), and are the constituents of freckles. Eumelanin is a black or brown pigment, and is mainly concerned with the protection of the skin by absorbing incoming UV radiation.

Pheomelanin is a reddish pigment and a very weak absorptive of UV radiation. It acts as a

photosensitizer, and increases sun sensitivity and skin ageing. Skin color is determined by the absolute amount and concentration of melanin in the skin.

Fairness cream (manufactured by Vasu Healthcare Pvt. Ltd., Vadodara, India) is a Polyherbal formulation that improves complexion, nourishes the skin, and makes it soft. It penetrates deep into the skin. It has nourishing and moisturizing activities. It contains Kumkumadi Tailam, extracts of Aloe barbadensis Mill., Rubia cordifolia Linn., Symplocos racemosa Roxb., cucumis sativus Linn., Carica papaya Linn. and Pushpanjan powder (Zinc Oxide) as its main constituents.

A clinical trial was planned to test the safety and efficacy of Fairness Cream as a result of repeated application for 4 weeks.

Aim of the Study

The purpose of this study was to evaluate safety and efficacy of polyherbal fairness cream as a result of repeated application for 4 weeks.

MATERIALS AND METHODS

This study was an open prospective, non-comparative Phase III clinical trial.

Criteria for selection of Volunteers / Patients

Volunteers with characteristic signs and symptoms i.e. dark Spot on face, Skin darkness etc. irrespective of their age, sex. Volunteers were selected on the basis of simple random sampling techniques.

Inclusion criteria

A 50 subjects (28 female and 22 male), age between 18 to 45 years, who willing to give informed written consent were included in the study.

Exclusion criteria

Following Volunteers / patients were excluded from the study

- Individuals with acne, skin infection over face
- Individuals on treatment with ultraviolet light, widespread active dermatitis or dermatitis on test area
- Immuno compromised individuals
- Those who not written consent
- Pregnant & Lactating

Study Procedure

All the volunteers who were willing to participate in the trial were screened for inclusion in the study. They were advice to clean a neck and face area thoroughly and then apply fairness cream twice daily for a period of 4 weeks.

Follow- up and assessment

All the patients were followed –up at weekly intervals for a period of 4 weeks. And the symptom score evaluation was done during each follow-up visit. Response to fairness Cream was evaluated on a 5-point visual analogue scale (0- Nil, 1- Mild, 2- Moderate, 3- Good, 4- Excellent)

Primary and Secondary endpoints

The predefined primary efficacy end point was a decreased in the symptoms score for dark complexion. The predefined secondary safety endpoints were acute and chronic safety, as assessed by the incidence of adverse events and patients compliance to therapy.

Adverse events

All the adverse events, either reported or observed by the patients, were recorded with information about severity, date of onset, duration and action taken regarding the study medication was predefined as “unrelated” (a reaction that dose not follow a reasonable temporal sequence from the administration of the drug), “possible” (follows a known response pattern to the suspected drug ,but could have been produced by the patient ‘s clinical state or other modes therapy administered to the patients),”probable”(follow a known response pattern to the suspected drug that could not be known characteristics of the patient’s clinical state).

Patients were allowed to voluntarily withdraw from the study, if they had experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For patients withdrawing

from the study, efforts were made to ascertain the reason for dropout. Non-compliance (define as failure to use less than 80 % of the medication) was not regarded as treatment failure, and reason for non-compliance were noted.

Statistical analysis

Statistical analysis was carried out using Fisher's exact test to find out the level of significance. The minimum level of significance was fixed at $p < 0.05$.

RESULTS

A total of 50 subjects (28 female and 22 male) were enrolled for the study. All subjects completed the study as planned. Significant reduction in dark complexion, increase in skin softness, and skin glowing effect was seen at the end of the study.

None of them was withdrawn from the therapy either for adverse events or other reasons.

Results indicated that Fairness Cream improves complexion, nourishes and makes the skin soft, and ensures ease of application and faster absorption, which provide better nourishment to the skin. It also effectively lightens overall complexion (Table 1).

There were no adverse effects reported during the study and compliance to the use of formulation was excellent (Table 2).

DISCUSSION

Melanin is the primary determinant of human skin color, Ultraviolet radiation causes to the nuclei of skin cells, leading to production of melanin. Fairness is determined directly by the amount of melanin in the cell. Melanin is a part of the cell's normal functioning; and increase production of melanin in human skin leads to development of a tan. Dark spot cause overproduction of the melanin in the skin cells exacerbate the uneven appearance of the skin surface. Regular use of the fairness creams helps reduce melanin production. Antioxidant herbs present in fairness cream protects the skin from premature ageing. For improvement in fairness, skin should be hydrated and protected from environmental damage. Fairness cream improves hydration and skin cell renewal at the epidermal cell layer, the excellent action of fairness cream might have been due to synergistic action of its ingredients.

Kumkumadi Tailam has used externally for abhyanga purpose. It enhance skin complexion. It is also used to treat acne, mole, skin diseases.⁶

Extract of Aloe vera (Kumari) has anti-inflammatory activity and protects from radiation induced dermatitis.^{7,8} It has wound healing activity.⁹⁻¹¹ and is a natural effective ingredient for improving skin hydration.¹²

Extract of Rubia cordifolia (Manjistha) having a free radical scavenging activity. An excess generation of free radical may cause skin disorder and disturbed the antioxidant system of the body. It contains anthraquinone which shows anti oxidant activity. Manjistha root extract is used for healing injuries lessens inflammation, spots and pigmentation and reducing wrinkles.¹³

Cucumber Sativus (Cucumber) is used in many anti-wrinkle and anti-ageing formulations. It is widely used in cosmetic industries. It has proven antioxidant activity.¹⁴

Carica Papaya (Papaya) is used as anti oxidant. It also glow the skin and widely used as cooling agent. Papaya fruit contains the enzyme papain. Papaya juice is to help reduce and attenuate freckles or brown spots due to exposure to sunlight, smoothing the skin and creating a healthier looking skin.^{15,16}

Extract of Symplocos racemosa (Lodhra) Lodhra is indicated in Ayurveda for wide range of properties. It is widely used in Ayurveda in large number of formulations where remedies are required for skin ailments & other health disorders. It is credited with cleaning and soothing properties.¹⁷

Pushpanjan powder (zinc oxide) works as a sunscreen agent by reflecting and scattering UV radiation. Sunscreen products reduce or prevent sunburn and premature aging of the skin.¹⁸ It enhanced "whitening" consumers have the benefit of a transparent natural product with high levels of protection from UVB/UVA sunlight, making the product aesthetically pleasing.¹⁹

Lemon oil and olive oil is widely used in cosmetic formulation. They have skin soothing and skin glowing activity.

CONCLUSION

The results of clinical study show that Fairness Cream is effective in lightening the skin complexion, and in making it soft and smooth. None of the volunteers experienced any hypersensitivity reactions or adverse effect. Therefore, it may be concluded that the Polyherbal Fairness Cream, is safe and efficacious.

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Table 1: Effect of Fairness Cream at end of the study

Effect		No. of Subjects					
		Reduction in dark complexion		Increased skin softness		Skin glowing effect	
Excellent	Responders	24	42**	18	30*	26	41**
Good		18		12		16	
Moderate	Non-responders	05	08	10	20	06	09
Mild		03		07		02	
Nil		00		03		01	

* p<0.05; ** p<0.01 – significance level

Table 2: Type of adverse effect

Parameters	On 1 st application	At end of the study
Erythema	Nil	Nil
Edema	Nil	Nil
Pruritus and Urticaria	Nil	Nil
Skin allergy	Nil	Nil
Irritation	Nil	Nil

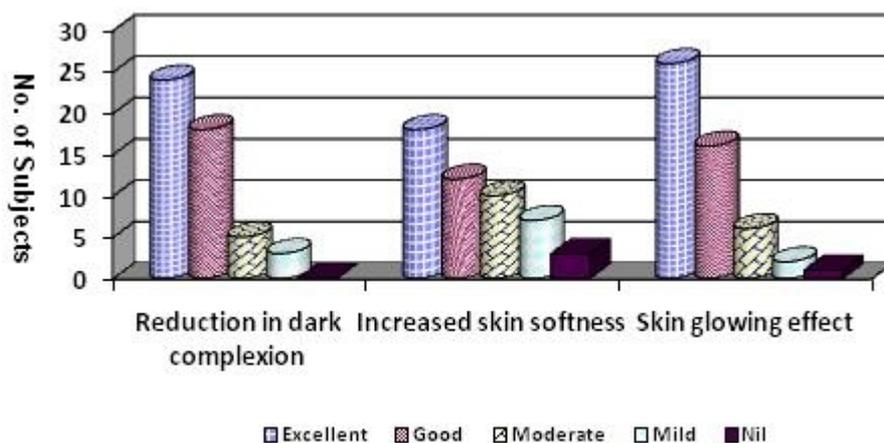


Figure-1: Effect of Fairness Cream at end of the study

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