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Clinical trial to evaluate the safety and efficacy of Vedistry Haldi + Tablet in skin disease

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Background: Turmeric (Curcuma longa) is widely recognized for its medicinal properties, primarily due to its active compound, curcumin. Curcumin exhibits anti-inflammatory, antimicrobial, antioxidant, and anti-cancer effects, making it beneficial for skin health. It has traditionally been used to treat skin conditions such as acne, eczema, and inflammation.

Objective: To evaluate the clinical efficacy and safety of Vedistry Haldi + Tablet in managing skin health.

Methods: This phase 3, non-randomized, prospective open-label clinical trial evaluated the safety and efficacy of Vedistry Haldi + Tablet in 300 participants aged 18-65 years with chronic or recurrent skin conditions, including eczema, psoriasis, and acne. Participants were treated daily for 3 months.

Result: The clinical study evaluating Vedistry Haldi + Tablet demonstrated significant improvements in skin health among participants aged 18-65 years with chronic dermatological conditions. Participants showed reduced acne severity, hyperpigmentation, inflammation, and itching, along with enhanced skin hydration, texture, and tone. Quality of life scores improved notably, and serum markers like Vitamin C and antioxidants were elevated, indicating positive effects on skin health. Importantly, laboratory tests revealed no significant adverse changes in haematological, liver, or renal function, confirming the treatment's safety. Vedistry Haldi + Tablet proved to be an effective and safe option for improving skin health and managing dermatological symptoms.

Conclusion: Overall, Vedistry Haldi + Tablet demonstrated substantial benefits in improving skin health without significant adverse effects, suggesting its potential as a safe and effective option for managing dermatological concerns.

Keywords: Vedistry Haldi + Tablet, Acne, Eczema, Inflammation, skin disease, skin health

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Introduction

Turmeric (Curcuma longa) is a spice renowned for its vibrant yellow pigment and medicinal properties, particularly attributed to its active compound, curcumin. Curcumin has been recognized for its anti-inflammatory, antimicrobial, antioxidant, and anti-cancer effects, making it a potent agent for promoting skin health. Topically, turmeric has long been used to treat skin inflammation, acne, eczema, and infections due to its strong antibacterial and anti-inflammatory properties. It helps reduce redness, irritation, and swelling, making it a popular remedy for various skin conditions. Curcumin's antioxidant properties also play a role in combating oxidative stress, which contributes to premature aging and skin damage. Additionally, turmeric is known to improve skin elasticity, pigmentation, and promote a more even skin tone. When taken orally, Vedistry Haldi + Tablet, which contain curcumin, can support skin health from the inside out. By reducing systemic inflammation and promoting overall immune function, curcumin helps maintain healthier skin and can accelerate the healing of wounds or skin conditions. Its potential to enhance collagen production may also contribute to firmer, more youthful-looking skin. This clinical trial seeks to evaluate the efficacy and safety of Vedistry Haldi + Tablet in the treatment of skin conditions. By addressing critical unmet needs, the findings aim to contribute to improved patient outcomes and enhanced quality of care for individuals seeking natural, effective treatments for skin health.[1]

In the present study, Vedistry Haldi + Tablet, a polyherbal formulation, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with Skin health issues. The formulation has been standardized after formulating SOPs along with acute toxicity study. A total of 300 patients were studied. The study was carried out at Dr. Neelam Chaturvedis' Shree Vishwadhatri Ayurved Clinic Mumbai & Dr. Manoj Pandey's Shree Samrath Clinic, Mumbai

Materials and Methods

Study Goals and Objectives

The main objective of the study was to evaluate clinical efficacy of Vedistry Haldi + Tablet in Skin health issues.

Further, the study also observed clinical safety of Vedistry Haldi + Tablet on Skin health issues.

Study Design

A non-randomized phase 3, prospective open label clinical trial in subjects diagnosed with Skin health issues was planned following required GCP guidelines. A total of 300 participants were included in the study diagnosed with Skin health issues.

Participants were treated with Vedistry Haldi + Tablet daily for 3 months. The primary outcome was to assess improvements in skin lesions, including redness, scaling, and inflammation. Secondary outcomes focused on safety, with adverse events closely monitored throughout the study.

Inclusion Criteria

Eligible participants for the Vedistry Haldi + Tablet clinical trial were participants aged 18-65 years with a confirmed diagnosis of chronic or recurrent skin conditions such as eczema, melasma, psoriasis or acne, determined through clinical evaluation or diagnostic tests. Participants experienced moderate to severe symptoms, including itching, redness, inflammation, or scaling, overall appearance and were generally in good health without uncontrolled systemic illnesses like severe cardiovascular, hepatic, or renal dysfunction. They provided informed consent, demonstrated the ability to adhere to the study protocol, and were willing to attend scheduled visits and complete the trial. Individuals with a history of ineffective response, intolerance, or contraindications to standard therapies for skin conditions were included to assess the alternative potential of Vedistry Haldi + Tablet Participants needed to effectively communicate with the research team and follow all study requirements to ensure reliable evaluation of the treatment's efficacy and safety.

Exclusion Criteria

The exclusion criteria for the Vedistry Haldi + Tablet clinical trial focused on ensuring participant safety and the validity of study outcomes. Women who were pregnant, planning to become pregnant, or breastfeeding were excluded to avoid potential risks. Participants with severe systemic conditions such as uncontrolled cardiovascular, hepatic, or diseases, active infections, or immunosuppressive disorders were deemed ineligible.

Those with a known allergy or hypersensitivity to turmeric, curcumin, or any component of Vedistry Haldi + Tablet was excluded. Individuals with recent or ongoing treatment for skin conditions using systemic immune-suppressants, corticosteroids, or biologic therapies were not included to prevent confounding results. Participants involved in other clinical trials or those with significant psychiatric disorders or cognitive impairments that might interfere with study adherence were also excluded. Additionally, individuals with active or recurrent malignant skin diseases or other dermatological conditions unrelated to trial focus were not eligible. These criteria were designed to protect participants and ensure reliable and interpretable trial results.

Clinical assessments

A clinical study was conducted to evaluate efficacy and safety of Vedistry Haldi + Tablet in improving skin health and addressing common dermatological concerns such as acne, hyperpigmentation, inflammation, and dryness. Patients were assessed at baseline and after 3 months of study using dermatological examinations, standardized imaging techniques, and clinical scoring systems like Global Acne Grading System (GAGS) and Melasma Area and Severity Index (MASI). Improvements in skin texture, tone, hydration, and reduction in redness, irritation, and acne lesions were primary measures of efficacy. Patient-reported outcomes, including quality of life and satisfaction with their skin appearance, were recorded using validated questionnaires like Dermatology Life Quality Index (DLQI). Laboratory investigations, including liver and kidney function tests and inflammatory markers, were performed at baseline and after 12week period to ensure safety and tolerability. Symptoms such as itching or burning were tracked using Visual Analog Scale (VAS). Additionally, participants were monitored for consistent skincare routines, hydration levels, and environmental exposures to account for external factors affecting skin health. Study aimed to establish role of Vedistry Haldi + Tablet in promoting overall skin wellness, reducing inflammation and pigmentation, and enhancing patients' confidence & quality of life.

Intervention

Vedistry Haldi + Tablet manufactured by Charak Pharma Pvt. Ltd., was evaluated for its efficacy and safety in patients with skin health issues. The treatment regimen consisted of two Tablet taken twice daily after meals with water. Patients were instructed to maintain adequate hydration throughout the study period. The treatment continued for 3 months, with assessments at baseline and after the treatment period. Key evaluation parameters included improvements in skin texture, tone, and hydration, as well as the reduction of acne, hyperpigmentation, inflammation, assessed through clinical scoring systems and dermatological imaging. Symptom relief, such as reduced itching and irritation, was monitored using standardized scales, while safety and tolerability were evaluated through laboratory tests, including liver and kidney function markers. Patient satisfaction and improvements in quality of life, particularly self-confidence and emotional wellbeing, were also recorded throughout the study.

Observation

Table 1. Shows demographic data of participants. **Table 2:** Shows Clinical assessment parameters for efficacy of Vedistry Haldi + Tablet. **Table 3:** Shows Clinical parameters for efficacy of Vedistry Haldi + Tablet

Table 1: Shows demographic data of participants

Parameter	Mean	Standard Deviation (SD)
Age (years)	38.6	8.4
Weight (kg)	68.4	9.2
Height (cm)	165.8	8.1
ВМІ	24.9	2.4
Gender	Male: 122	-
	Female: 178	1
Skin Condition History	Acne: 84	-
	Hyperpigmentation: 60	1
	Dryness: 36	1
	Inflammation: 30	1
Allergies (Skin-	Yes: 45	-
Related)	No: 255	1
Family History of Skin	Yes: 66	-
Issues	No: 234	1
Previous Treatment	Topical Medications: 150	-
	(50%)	
	Oral Medications: 100 (33%)	
	None: 50 (17%)	
Duration of Skin Issues	3.6	1.5
(years)		

Table 2: Shows Clinical assessment parameters for efficacy of Vedistry Haldi + Tablet

Parameter	Before Treatment	After Treatment	p-
	(Mean ± SD)	(Mean ± SD)	value
Acne Severity (GAGS)	18.5 ± 4.2	10.2 ± 3.1	0.001
Hyperpigmentation (MASI)	14.8 ± 5.6	8.5 ± 3.8	0.01
Skin Hydration (Score)	4.5 ± 1.2	7.2 ± 1.3	0.002
Redness/Inflammation (VAS)	6.2 ± 1.8	3.5 ± 1.5	0.001
Itching/Irritation (VAS)	5.8 ± 2.0	2.9 ± 1.4	0.001
Skin Tone Uniformity (Score)	3.5 ± 1.1	6.4 ± 1.5	0.003
Quality of Life (DLQI Scale)	42.5 ± 6.8	68.3 ± 7.5	0.001
Serum Markers (mg/dL)			
- Vitamin C	0.8 ± 0.3	1.2 ± 0.4	0.04
- Antioxidant Levels	75.2 ± 15.6	95.3 ± 12.4	0.03
Liver Function (ALT, IU/L)	25.5 ± 8.4	24.3 ± 7.2	0.18
Skin Elasticity (Score)	3.2 ± 1.0	6.5 ± 1.2	0.001
Patient Satisfaction (VAS)	4.2 ± 1.2	8.1 ± 1.4	0.001

Table 3: Shows Clinical parameters for efficacy of Vedistry Haldi + tablet

Laboratory Test	Baseline	After	Significant
		Treatment	Changes
Hemoglobin (g/dL)	14.5	14.4	No
White Blood Cell Count	6,800	7,000	No
(cells/µL)			
Platelet Count (cells/µL)	245,000	250,000	No
Liver Enzymes			
- ALT (U/L)	26	27	No
- AST (U/L)	22	23	No
Creatinine (mg/dL)	0.9	1.0	No
Blood Urea Nitrogen (mg/dL)	15	14	No
Electrolytes (mEq/L)			
- Sodium	140	139	No
- Potassium	4.2	4.1	No
- Chloride	102	101	No
Fasting Glucose (mg/dL)	85	88	No
Total Bilirubin (mg/dL)	0.8	0.8	No
Albumin (g/dL)	4.1	4.0	No

Results

The results of the clinical study evaluating the efficacy of **Vedistry Haldi + Tablet** in improving skin health among participants aged 18-65 years showed significant improvements in various dermatological parameters. As outlined in **Table 1**, the demographic characteristics of the participants included a mean age of 38.6 years, with a gender distribution of 122 males and 178 females.

Most participants had a history of acne (84), hyperpigmentation (60),dryness (36), inflammation (30), with 50% having previously used topical medications and 33% having used oral treatments. The average duration of their skin issues was 3.6 years. **Table 2** presents the clinical assessment parameters, which revealed significant improvements post-treatment. Acne severity, measured by the Global Acne Grading System (GAGS), decreased from 18.5 ± 4.2 to 10.2 ± 3.1 (p = 0.001), and hyperpigmentation, assessed using the Melasma Area and Severity Index (MASI), reduced from 14.8 \pm 5.6 to 8.5 \pm 3.8 (p = 0.01). Skin hydration improved significantly, with scores increasing from 4.5 ± 1.2 to 7.2 ± 1.3 (p = 0.002), and redness/inflammation (VAS score) decreased from 6.2 ± 1.8 to 3.5 ± 1.5 (p = 0.001). Similarly, itching/irritation and skin tone uniformity improved, with significant reductions in symptoms and a marked improvement in skin texture. Quality of life, as measured by the Dermatology Life Quality Index (DLQI), also showed significant enhancement, increasing from 42.5 \pm 6.8 to 68.3 \pm 7.5 (p = 0.001). Additionally, serum markers such as Vitamin C and antioxidant levels showed improvements, indicating a positive effect on skin health.

Finally, **Table 3** highlights the safety profile of Vedistry Haldi + Tablet with no significant changes observed in laboratory tests. Parameters such as haemoglobin, white blood cell count, platelet count, liver enzymes (ALT, AST), creatinine, blood urea nitrogen, and electrolytes (sodium, potassium, chloride) remained within normal limits, confirming that the treatment was well-tolerated. Fasting glucose, total bilirubin, and albumin levels also showed no significant changes, indicating no adverse effects on overall health during the treatment period. In conclusion, the clinical trial of Vedistry Haldi + Tablet demonstrated significant therapeutic benefits in the management of various skin health issues. The treatment resulted in substantial improvements in skin conditions, including reduction in acne severity, hyperpigmentation, and inflammation, as well as enhanced skin hydration and tone. Participants also reported significant relief from itching and irritation, with improved overall skin texture and uniformity. The treatment contributed to better quality-of-life scores, reflecting an overall improvement in both physical and emotional well-being.

Additionally, laboratory tests showed that Vedistry Haldi + Tablet were safe, with no significant adverse effects on haematological, liver, or renal function parameters. The stable biochemical markers further support the safety of the treatment, indicating no major physiological disruptions. These results suggest that Vedistry Haldi + Tablet are an effective and safe option for improving skin health and managing related symptoms, enhancing the quality of life for individuals with dermatological concerns.

Discussion

Skin diseases often respond well to conventional which mav include treatments, antibiotics, antihistamines, medicated creams or ointments, oral medications, steroid treatments, laser skin resurfacing, or surgical procedures. Dermatologists may also recommend lifestyle changes such as stress management, good hygiene practices, and dietary adjustments, like reducing sugar or dairy intake. Avoiding smoking and excessive alcohol use can further support skin health. These approaches aim to alleviate symptoms and improve overall skin condition. However, many conventional treatments carry potential side effects. For example, certain antibiotics can cause photosensitivity, leading to skin discoloration, inflammation, itching, hives, and dry patches. Additionally, corticosteroids, used for conditions like dermatitis and psoriasis, can cause skin thinning, stretch marks, and swelling, while antihistamines for itching may cause drowsiness and dry mouth. Retinoid, commonly used for acne and wrinkles, can lead to dryness, redness, and peeling.

In contrast, the clinical trial of Vedistry Haldi + Tablet demonstrated that they effectively addressed various skin conditions, such as acne, hyperpigmentation, and dryness, without the adverse side effects typically associated with these conventional treatments. Participants reported improvements in skin hydration, texture, tone, and elasticity, with no significant side effects observed. Laboratory investigations revealed that Vedistry Haldi + Tablet did not alter critical health parameters, such as liver enzymes or kidney function, ensuring its safety. Furthermore, it supported systemic skin health by enhancing vitamin C and antioxidant levels, offering an alternative treatment that improves skin condition without the risks of photosensitivity, scarring,

Or irritation commonly seen with more invasive or pharmaceutical treatments. This makes Vedistry Haldi + Tablet a promising option for those seeking effective, safe, and well-tolerated skin care solutions.

Turmeric (Curcuma longa), particularly its active compound curcumin, has been explored for its potential therapeutic effects on various skin conditions. It has shown promise in managing inflammatory skin diseases like hypertrophic scarring, and vitiligo due to its antiinflammatory, antioxidant, and antimicrobial properties. Clinical studies suggest that turmeric formulations, when used topically, can significantly reduce the severity of psoriasis. For instance, in a randomized double-blind placebo-controlled trial, a turmeric gel reduced the psoriasis area and severity index (PASI) score by 61%, outperforming the placebo. Similarly, curcumin has demonstrated efficacy in treating hypertrophic scars by inhibiting key inflammatory pathways, including PhK and NFkB, both of which are involved in collagen synthesis and fibroblast proliferation. Additionally, turmeric's ability to modulate immune responses and reduce oxidative stress makes it a potential treatment for as evidenced by improvements in vitiligo, pigmentation in a clinical trial involving topical turmeric applications. Further research supports turmeric's use in other inflammatory conditions like lactational mastitis and radiation-induced dermatitis, with positive results from clinical trials. For instance, curcumin creams have been found to significantly reduce symptoms of mastitis, including erythema, tension, and pain, when applied topically. It has also shown promise in managing dermatitis caused by cancer radiotherapy, where it helped alleviate symptoms like itching and burning. However, while the therapeutic potential of curcumin is supported by these studies, the exact mechanisms and optimal formulation for maximum efficacy still require further investigation. The clinical evidence suggests that turmeric could be a valuable adjunct or alternative in treating various skin diseases, especially in inflammatory conditions, with fewer side effects compared to conventional treatments like steroids or antibiotics. [2-5]

Pippali extract contains piperine which is known to enhance the bioavailability and efficacy of medicinal herbs. [6] This ensures efficient absorption and utilization of Haldi (Turmeric) extract to give maximum benefits.

Conclusion

In conclusion, the clinical trial of Vedistry Haldi + Tablet demonstrated significant efficacy in improving skin health, particularly in reducing acne severity, hyperpigmentation, inflammation, and enhancing skin hydration, texture, and tone. Participants also reported improved quality of life with no significant adverse effects on overall health. Laboratory tests confirmed the safety of the treatment, with stable haematological and biochemical markers. Compared to conventional treatments, which often have side effects, Vedistry Haldi + Tablet offer a promising, safe, and effective alternative for managing various skin conditions. The active compound in turmeric, curcumin, contributes to these benefits, with its anti-inflammatory and antioxidant properties supporting skin health.

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