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Shampoo Containing ScalpCleanse® vs Marketed Shampoo in Dandruff Management: A Randomized, Double-Blind, Comparative Study

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Abstract: ***This randomized, double-blind clinical trial compares the safety and efficacy of an anti-dandruff shampoo containing ScalpCleanse®, a proprietary combination of phytochemicals, to a standard ketoconazole-zinc pyrithione shampoo. Forty participants with mild to moderate dandruff used one of the two shampoos over 30 days. Clinical parameters of dandruff severity, scaling (adherent and non-adherent), erythema, scalp sebum levels, itching, and dryness were evaluated at multiple time points, along with participant self-assessment and safety and tolerability. Results revealed significant improvements in both groups, including significant and comparable reductions in adherent and non-adherent dandruff by the end of the study. Both shampoos also significantly reduced erythema, itching, dryness and sebum production. Shampoo containing ScalpCleanse® showed a numerically greater reduction in erythema and dryness. Both products were well-tolerated with no serious adverse events reported. The study concluded that shampoo containing ScalpCleanse® is equally effective and safe as the marketed ketoconazole and zinc pyrithone shampoo in the treatment of dandruff and associated symptoms. An anti-dandruff shampoo containing ScalpCleanse® presents a viable alternative to synthetic antifungal shampoos.***

Keywords: ScalpCleanse®, dandruff treatment, phytochemical extract, scalp itching, sebum control

1. Introduction

Dandruff is a prevalent condition on the scalp, affecting a huge part of the human population and usually causes discomfort, embarrassment and interference with the quality of life. It is characterized by excessive flaking of the scalp, itching, and inflammation, but pathogenesis includes several causal factors like an overload of *Malassezia* yeast, secretion of sebum, and an inherent genetic predisposition for this skin condition [1]. Dandruff may not be a serious threat to health, but it certainly causes greater agony and discomfort. Dermatological conditions like seborrheic dermatitis or an unhealthy scalp are associated with it. The prevalence of dandruff in South Asia is 60.1%, whereas in the world it is 50% (4). Although often seen as a minor problem, dandruff can have a significant negative impact on self-esteem and can potentially develop into more serious scalp issues if not addressed [2]. Dandruff severity varies, with trapped scales in dense hair possibly preventing shedding. It may contribute to telogen effluvium, exacerbate androgenetic alopecia, and increase hair shedding, while some anti-dandruff agents like ketoconazole may slow hair loss progression [3]. Currently, treatment options revolve around medicated anti-dandruff shampoos enriched with antifungal agents like ketoconazole and zinc pyrithione that are highly effective in curbing *Malassezia* growth as well as giving symptomatic relief. However, the long-term use of synthetic antifungal drugs has led to a demand for alternative therapies, due to associated side effects such as scalp irritation, dryness, hair discolouration, and relapse upon withdrawal [4].

In recent years, the interest in herbal formulations for anti-dandruff has increased rapidly due to their being expected to show an antifungal, anti-inflammatory, and soothing effect on the scalp [5]. Some herbal ingredients, such as neem, coconut

oil, tea tree oil, and rosemary extract, have shown promising antimicrobial and therapeutic applications to constitute good alternatives to traditional anti-fungal shampoos. In the face of increasing preference among consumers toward natural, safer hair treatments, herbal-based formulations validated scientifically are currently making up the research and development effort [6-7].

This study was conducted to evaluate the efficacy and safety of a shampoo containing ScalpCleanse® with marketed ketoconazole and zinc pyrithione Shampoo. This involved measurement of clinical parameters of severity of dandruff, scalp health, relief in symptoms, and self-reported assessment. This evidence would strengthen claims that shampoo containing ScalpCleanse® has comparable efficacy to the currently available synthetic anti-fungal shampoos. The results of this research may help in providing guidelines to healthcare professionals as well as consumers regarding decision-making concerning precision scalp care treatments. This study aims to evaluate the safety and efficacy of a shampoo containing ScalpCleanse® in comparison with a marketed antifungal shampoo for managing dandruff and associated scalp conditions.

2. Methodology

2.1 Study Design

This study was a double-blind, randomized, controlled, interventional, parallel-group clinical trial designed to evaluate the therapeutic efficacy and safety of a Test product (anti-dandruff shampoo containing ScalpCleanse®) compared to a comparator (ketoconazole and zinc pyrithione shampoo). The study was conducted in compliance with Good Clinical Practice (GCP) guidelines and ethical principles outlined in the Declaration of Helsinki. The study was conducted at Lokmanya Medical Research Centre and Hospital. The study was initiated only after written approval was obtained from the Institutional Ethics Committee (IEC) of Lokmanya Medical Research Centre. This study was conducted from September 2, 2024, to October 30, 2024.

2.2 Study Population

Inclusion Criteria:
Males and females aged 18 to 55 years (both inclusive) with a clinically confirmed diagnosis of dandruff of the scalp, having a combined score for scaling and erythema between 2 and 4 during screening, were included in the study. Participants who were ready to refrain from using any topical medications that could affect trial results, including medicated shampoos, oils, antibiotics, or oral antifungal agents during the treatment and relapse periods, were included. Participants showing ability and willingness to complete study-related questionnaires, records, and diaries, attend all scheduled study visits, and provide voluntary, written informed consent to participate in the study were included in this study.

Exclusion Criteria:
Participants with a history or presence of compromising dermatosis elsewhere on the skin; presence of Parkinson's disease, HIV, infections, or disorders of the central nervous system were excluded from the study. Participants using anti-dandruff agents in the past 14 days or having skin conditions that could interfere with the diagnosis or assessment of dandruff, including psoriasis, acne, and atopic dermatitis, were excluded from the study. Additionally, participants who had used any treatment within two weeks before baseline that could affect trial results, such as topical steroids, topical retinoids, topical anti-inflammatory agents, topical antibiotics, oral antifungal agents, or topical treatments for adherent dandruff (including coal tar preparations, anti-dandruff shampoos, oils, gels, creams, conditioners, or antihistamines) were excluded. Pregnant or lactating females, those with a positive urine pregnancy test, or those planning to become pregnant or not using reliable contraception were also excluded. Furthermore, individuals who had participated in other clinical trials within the last 90 days before screening or had any condition that, in the investigator's opinion, could preclude their ability to complete the study or confound results were excluded.

2.3 Intervention Details

The test product contains a combination of phytochemicals from *Caesalpinia sappan, Saussurea lappa, Rosmarinus officinalis L*., and *Arctium lappa*. The comparator (marketed) shampoo contained Ketoconazole 2% w/w and Zinc Pyrithione 1% w/w as active ingredients.

Participants in both groups were instructed to use approximately 10–12 mL of their assigned shampoo three times per week for 30 consecutive days, applying it during routine hair cleansing.

2.4 Clinical Study Procedure:

This randomized, comparative clinical study was conducted to evaluate the efficacy, safety, and tolerability of the shampoo containing ScalpCleanse® compared to a marketed product. A total of 42 participants were enrolled after obtaining written informed consent and were randomly assigned in a 1:1 ratio using a computer-generated randomization list prepared by a biostatistician. Two participants from the test group (shampoo containing ScalpCleanse®) discontinued due to loss to follow-up, resulting in 40 participants (20 per group) completing the study, as shown in Figure 1. Before baseline assessments, participants were instructed to avoid washing their hair with any product for the duration of the one-week washout period.

Efficacy and safety assessments were performed at multiple time points: screening, baseline (Day 1), Day 3, Day 9, Day 15, Day 21 (for selected subjective parameters), and Day 30. The primary efficacy endpoints included the evaluation of dandruff severity, scaling (adherent and non-adherent), erythema, scalp sebum levels, itching, dryness, and participants' subjective perceptions of scalp and hair condition. Dandruff severity was assessed using a 4-point ordinal scale based on clinical evaluation, where 0 indicated no scaling, 1 indicated mild scaling, 2 indicated moderate scaling, and 3 indicated severe scaling. Both adherent and non-adherent dandruff were evaluated at baseline, Day 3, Day 9, Day 15, and Day 30. Additionally, the appearance of dandruff and scalp condition was captured through phototrichograms at baseline, Day 3, Day 15, and Day 30 to provide objective visual images.

The degree of erythema was assessed by the investigator using a validated 4-point scale, where 0 represented no erythema, 1 indicated mild erythema, 2 moderate erythema, and 3 severe erythema. These evaluations were conducted at screening, baseline, Day 3, Day 9, Day 15, and Day 30. Scalp sebum production was quantitatively measured in all participants using a Sebumeter® at baseline, Day 15, and Day 30. All measurements were conducted under controlled environmental conditions (temperature 20 ± 1°C and relative humidity 40–60%) following a 30-minute acclimatization period in a controlled room to ensure consistency.

Scalp itching and dryness were evaluated at each visit using a 4-point scale, where 0 indicated no symptoms, 1 indicated mild symptoms, 2 moderate symptoms, and 3 severe symptoms. These assessments were performed at screening and all subsequent visits through Day 30.

To assess subjective perceptions of product efficacy and hair and scalp health, participants completed a questionnaire using a 5-point scale, where 0 indicated "very much worsened," 1 "worsened," 2 "no change," 3 "improved, and 4 "very much improved." This questionnaire included assessments of scalp hydration, itchiness, redness, stickiness, cleanliness, hair smoothness and softness, dandruff content, scalp calmness, ease of dry and wet hair combing. These responses were recorded at baseline, Day 3, Day 9, Day 15, Day 21, and Day 30.

The in-use tolerance of both products was evaluated based on participants' experiences of four potential adverse reactions: tingling, burning sensation, allergic reactions, and eye stinging. Each of these was rated using a 4-point scale, where 0 indicated no reaction, 1 a slight but tolerable reaction (mild), 2 a noticeable reaction causing some discomfort (moderate), and 3 an intense reaction causing significant discomfort or distress (severe). These parameters were assessed from Day 3 through Day 30.

Adverse events (AEs), including their frequency and severity, were recorded throughout the study duration. Investigators evaluated all reported AEs for their relationship to the study products. Additionally, compliance with product use and overall tolerability were monitored from baseline through Day 30 to ensure participant adherence and evaluate the safety profile of the investigational product.

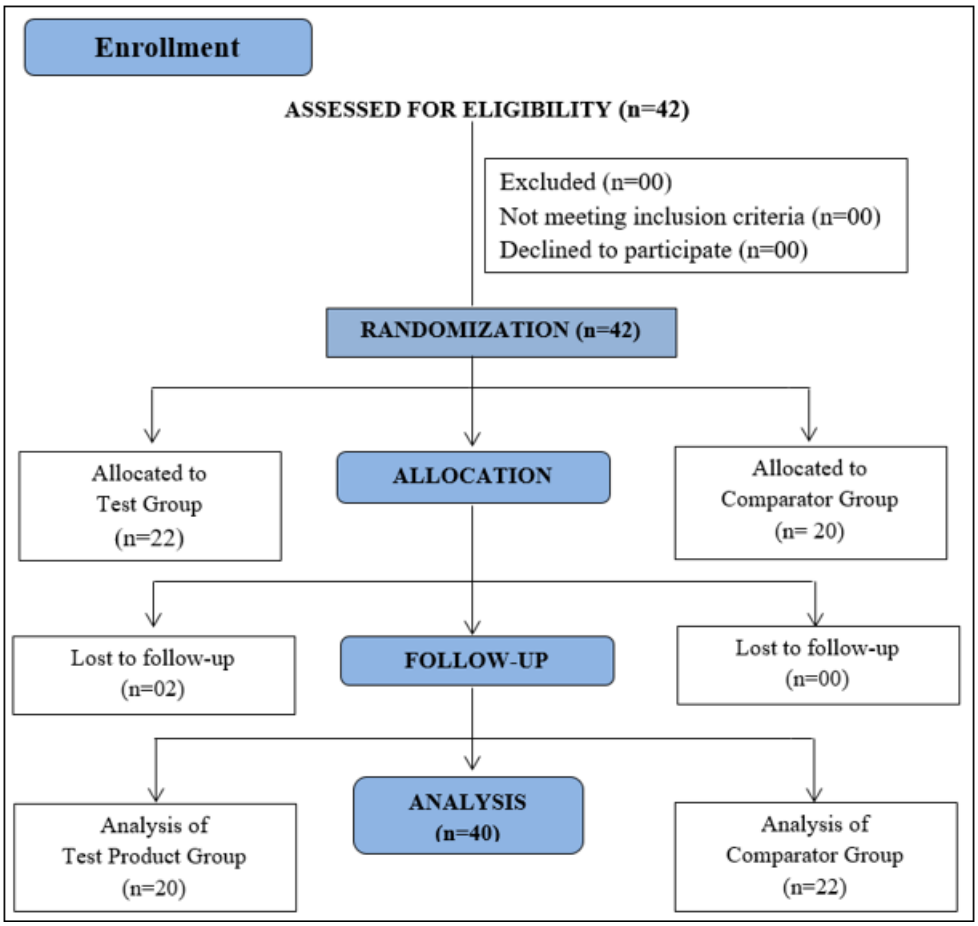


Figure 1: CONSORT diagram for the study

2.6 Statistical Analysis

All analyses were done using SPSS software. All data were summarized with descriptive statistics (number of participants, mean, standard deviation, minimum, median, and maximum) for continuous endpoints and frequency and percentage for categorical endpoints. Primary and secondary efficacy endpoints were intended to be analyzed using the PP (per protocol) population and Safety variables as per mITT (modified intention-to-treat).

Parameters such as adherent and non-adherent dandruff, erythema, itching, dryness, and sebum production were analyzed by Student's t-test (dependent) & Wilcoxon Signed-

Rank Test, and between-group comparisons were conducted using the Mann-Whitney U Test. P-value of <0.05% was considered a significant value. Demographic parameters are analyzed by descriptive statistics such as mean and standard deviation.

3. Results

3.1 Assessment of demographic details and anthropometric parameters:

The demographic characteristics, including gender distribution and age, showed no clinically significant differences between the groups. However, there were comparatively higher numbers of females than males in the study across groups. The anthropometric parameters, i.e., weight, height, and BMI, also showed no significant variations as represented in Table 1.

Table 1: Demographic details

Group	Test Product		Comparator Group	
Gender	Male (n=05)	Female (n=15)	Male (n=03)	Female (n=17)
Average age (years)	29.60 ± 7.30	28.00 ± 5.54	31.67 ± 4.73	27.65 ± 8.22
Total average age (years)	28.40 ± 5.86		28.25 ± 7.83	
Weight (kg)	62.20 ± 5.25	65.61 ± 10.80	57.73 ± 2.05	68.70 ± 8.57
BMI (kg/m^2)	25.67 ± 4.91	25.39 ± 4.64	23.64 ± 2.05	25.80 2.79

Data is represented as Mean ± S.D.

3.2 Assessment of Adherent and Non-Adherent Scaling

At the baseline average participants in both groups had mild to moderate adherent scaling; following the treatment, scaling improved gradually and at the end of the study, both groups reported no scaling with a significant 91.89% reduction in the Test group and a 94.44% reduction in the comparator group. No significant difference was observed in between-group analysis, as represented in Table 2 and Figure 2.

Non-adherent dandruff shows a similar trend, where at the baseline, both groups had mild to moderate non-adherent scaling. Non-adherent scaling reduces gradually over time, and the end of the study test group showed a significant 91.67% reduction, and the comparator group showed a significant 94.59% reduction. These results show comparable efficacy of both the products which is also indicated by the non-significant difference between group analysis, represented in Table 2 and Figure 2.

Table 2: Assessment of adherent and non-adherent dandruff

Group	Baseline	Day 3	Day 9	Day 15	Day 30
Adherent Dandruff					
Test Group	1.85±0.37	1.75±0.44 (5.41%)	1.15±0.67 (37.84%)	0.55±0.60 (70.27%)	0.15 ±0.37 (91.89%)
P-value Within		0.163	<0.001	<0.001	<0.001
Comparator Group	1.80±0.41	1.75±0.44 (2.78%)	1.10±0.64 (38.89%)	0.75±0.55 (58.33%)	0.10±0.31 (94.44%)
P-value Within		0.330	0.001	<0.001	<0.001
P-value Between	0.795	0.795	0.944	0.267	0.992
Non-Adherent Dandruff					
Test Group	1.80±0.41	1.75±0.44 (2.78%)	1.30±0.73 (27.78%)	0.60±0.60 (66.67%)	0.15±0.37 (91.67%)
P-value Within		0.330	0.005	<0.001	<0.001
Comparator Group	1.85±0.37	1.75±0.44 (5.41%)	1.30±0.73 (29.73%)	0.70±0.47 (62.16%)	0.10±0.31 (94.59%)
P-value Within		0.163	0.005	<0.001	<0.001
P-value Between	0.795	0.795	0.780	0.779	0.749

Data are presented as Mean ± SD (percent change). Within-group comparisons were performed using the Student's t-test (dependent) & Wilcoxon Signed-Rank Test, and between-group comparisons were conducted using the Mann-Whitney U Test. Statistical significance was set at P < 0.05.

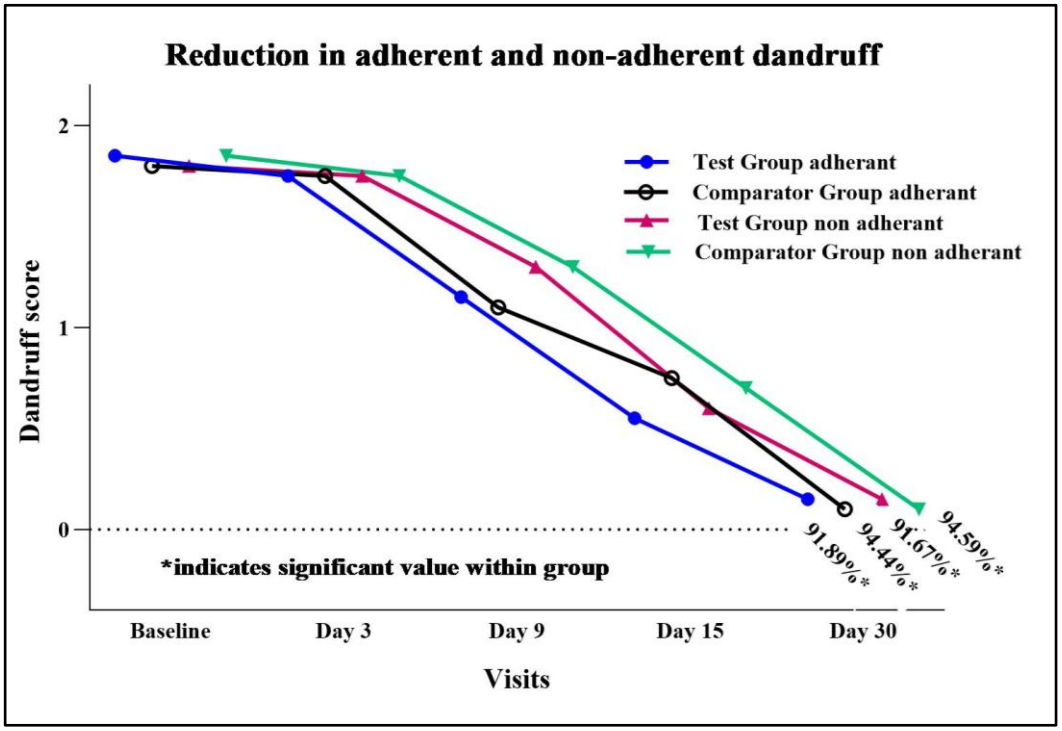
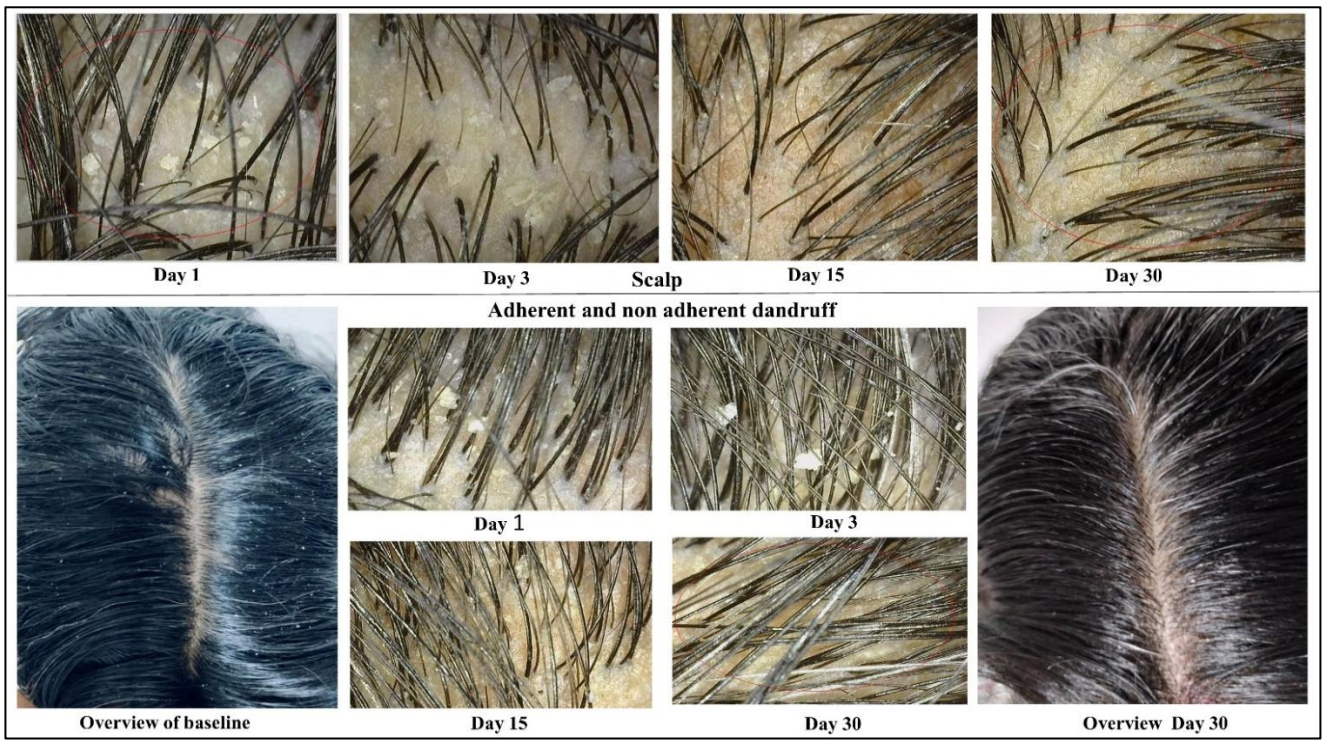


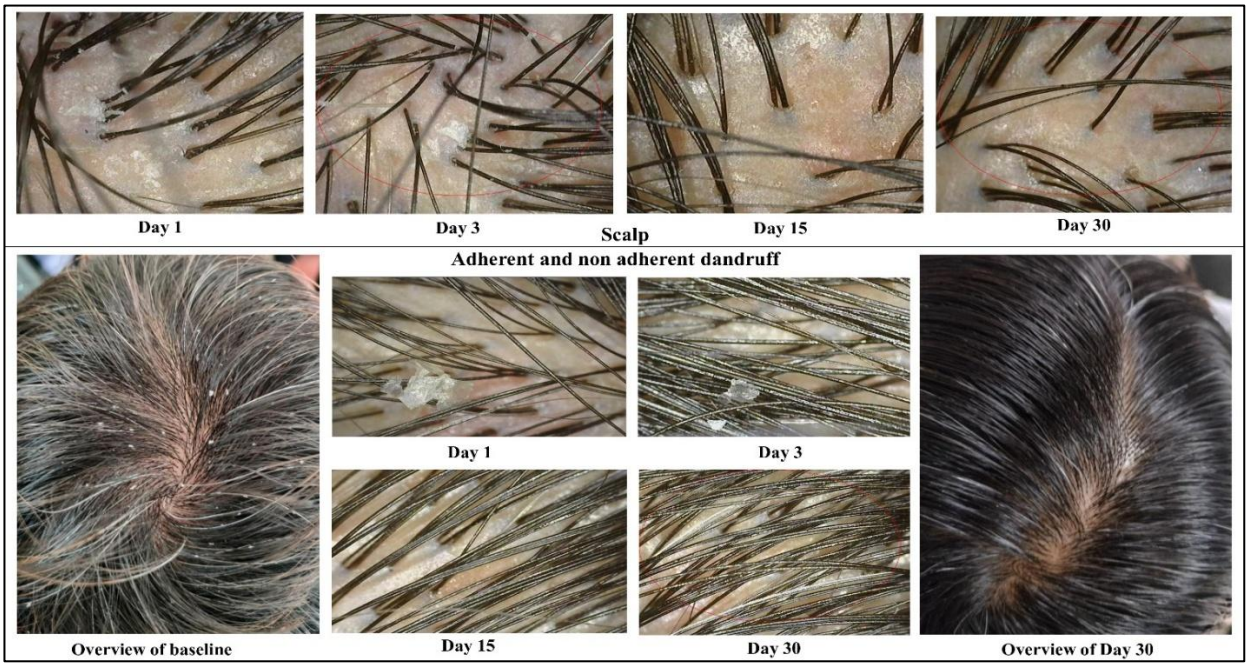
Figure 2: Reduction in Adherent and non-adherent score

3.3 Dandruff Scaling Measurement through Phototrichogram

Phototrichogram images of all participants were taken and representative images of both genders from the test group are represented in Figure 3. Visual examination reveals a reduction in overall dandruff content as well as adherent and non-adherent dandruff content as compared to baseline, which is also evident by the reduction in mean score of adherent and non-adherent dandruff scores.



(a)



(b)

Figure 3: Representative Phototrichogram Images Depicting Reduction in Adherent and Non-Adherent Dandruff Following Treatment with (a) Anti-Dandruff Shampoo containing ScalpCleanse® and (b) Comparator Shampoo

3.4 Assessment of erythema

At baseline, participants in both groups had moderate to severe erythema. Following the intervention gradual reduction in erythema score was observed in both groups, and participants reported only mild to moderate scores in both groups. The test group showed a significant reduction of 57.89% while the comparator group showed a 46% reduction. The test group showed better reduction in erythema, although no significant difference was observed in between-group analysis. These results show that the test product is more effective than the comparator (marketed) product at reducing erythema, with significant improvements starting on Day 9 and continuing until Day 30. This demonstrates the test product's potential as a successful erythema reduction intervention.

Table 3: Assessment of Change in Degree of Erythema score

Group	Screening	Baseline	Day 3	Day 9	Day 15	Day 30
Erythema						
Test Group	2.85 ±0.37	2.90 ± 0.31 (1.75%)	2.70±0.47 (5.26%)	2.20±0.70 (22.81%)	1.65±0.59 (42.11%)	1.20± 0.77 (57.89%)
P-value Within		0.330	0.186	0.006	<0.001	<0.001
Comparator Group	2.50±0.51	2.55±0.51 (2%)	2.45±0.51 (2%)	2.10±0.64 (16%)	1.80±0.41 (28%)	1.35±0.75 (46%)
P-value Within	-	0.330	0.577	0.028	0.002	0.001
P-value Between	0.060	0.992	0.617	0.254	0.036	0.131

Data are presented as Mean ± SD (percent change). Within-group comparisons were performed using the Student's t-test (dependent) & Wilcoxon Signed-Rank Test, and between-group comparisons were conducted using the Mann-Whitney U Test. Statistical significance was set at P < 0.05.

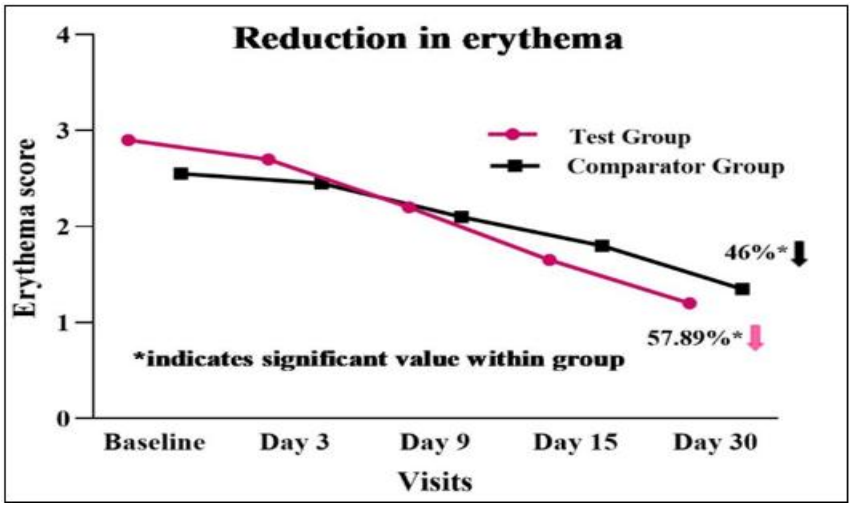


Figure 4: Reduction in erythema

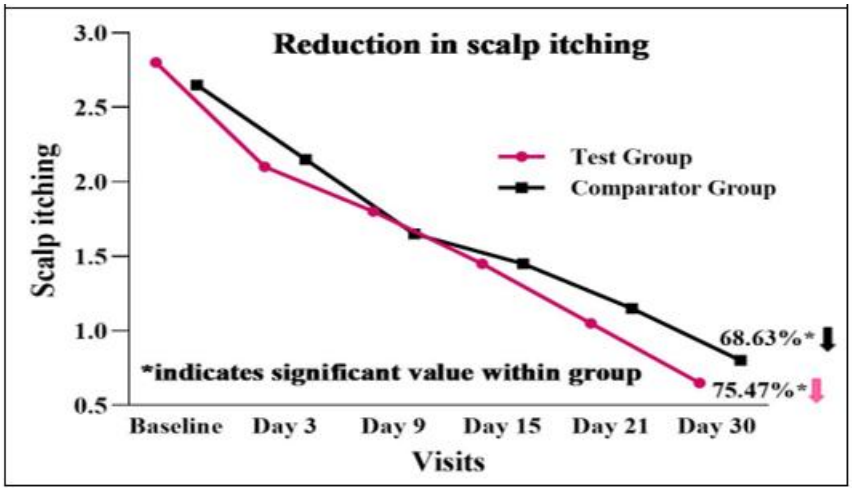


Figure 5: Reduction in scalp itching

3.5 Assessment of the scalp itching

Significant gradual reduction was observed in both groups, at baseline, participants averagely to have moderate to severe itching, which was reduced to none to mild itching at the end of the study. The test group shows a 75.47% reduction while the comparator group shows 68.63% as compared to baseline. The test group shows better efficacy in reducing scalp itching over the marketed product, although the difference was not statistically significant, as represented in Table 4 and Figure 5.

Table 4: Assessment of Change in Degree of Itching and Dryness

Group	Screening	Baseline	Day 3	Day 9	Day 15	Day 21	Day 30
Scalp Itching							
Test Group	2.65±0.49	2.80±0.41 (5.66%)	2.10±0.55 (20.75%)	1.80±0.52 (32.08%)	1.45±0.51 (45.28%)	1.05±0.69 (60.38%)	0.65±0.75 (75.47%)
P-value Within		0.083	0.003	<0.001	<0.001	<0.001	<0.001
Comparator Group	2.55±0.51	2.65±0.49 (3.92%)	2.15±0.59 (15.69%)	1.65±0.49 (35.29%)	1.45±0.51 (43.14%)	1.15±0.67 (54.90%)	0.80±0.70 (68.63%)
P-value Within		0.163	0.002	<0.001	<0.001	<0.001	<0.001
P-value Between	0.596	0.795	0.424	0.779	0.617	0.297	0.294
Dryness							
Test Group	2.70±0.47	2.75±0.44 (1.85%)	2.40±0.50 (11.11%)	2.30±0.47 (14.81%)	2.25±0.44 (16.67%)	1.65±0.49 (38.89%)	1.30±0.47 (51.85%)
P-value Within		0.666	0.093	0.041	0.028	<0.001	<0.001
Comparator Group	2.65±0.49	2.70±0.47 (1.89%)	2.30±0.47 (13.21%)	2.20±0.41 (16.98%)	2.10±0.55 (20.75%)	1.65±0.49 (37.74%)	1.40±0.50 (47.17%)
P-value Within		0.666	0.015	0.001	0.005	<0.001	<0.001
P-value Between	0.795	0.992	0.881	0.992	0.889	0.826	0.352

Data are presented as Mean ± SD (percent change). Within-group comparisons were performed using the Student's t-test (dependent) & Wilcoxon Signed-Rank Test, and between-group comparisons were conducted using the Mann-Whitney U Test. Statistical significance was set at P < 0.05.

3.6 Assessment of dryness

Significant reduction of 51.85% was observed in the Test group, while the comparator group showed 47.17% reduction. At baseline, participants reported moderate to severe dryness in both groups, which decreased gradually and at the end of the study, both groups reported mild to moderate dryness. The test group showed greater efficacy in reducing dryness over the comparator group, although no significant difference was observed in between group analysis. Represented in table 4 and figure 6.

3.7 Assessment of product tolerance

The participants' tolerance toward anti-dandruff shampoos was evaluated through four reactions: tingling, burning, allergic response, and stinging of the eyes. Participants rated these symptoms on a 0-3 scale, where 0 indicates no symptom and 3 indicates severe symptoms experienced. By the third day, after the first wash, the test shampoo participant groups reported two moderate tingling sensations along with two mild burning sensations. The comparator group had one mild burning sensation along with two mild tingling sensations. No allergic reactions were noted, and these symptoms did not continue following the treatment. These results suggest safety profile for the products.

3.8 Assessment of Sebum Production

Following the treatment, Sebumeter® levels reduces gradually, with a significant reduction at day 15 in both groups. At the end of the study both groups show significant reduction, test group shows 32.04% reduction while 31.04% reduction was observed in the comparator group. The test group showed slightly better efficacy in reducing sebum production over the marketed product, although no significant

difference was observed in between group analysis. These results suggest the ability of anti-dandruff shampoo containing ScalpCleanse® in reducing sebum production, depicted in Table 5 and Figure 6.

Table 5. Assessment of Sebum Production

Group	Baseline	Day 15	Day 30
Test product	109.85±6.69	84.15±3.23 (23.40%)	74.65±3.07 (32.04%)
P-value Within		<0.001	<0.001
Comparator Group	109.55±6.14	85.8±3.35 (21.68%)	75.55±3.28 (31.04%)
P-value Within		<0.001	<0.001
P-value Between	0.883	0.354	0.583

Data are presented as Mean ± SD (percent change). Within-group comparisons were performed using the Student's t-test (dependent) & Wilcoxon Signed-Rank Test, and between-group comparisons were conducted using the Mann-Whitney U Test. Statistical significance was set at P < 0.05.

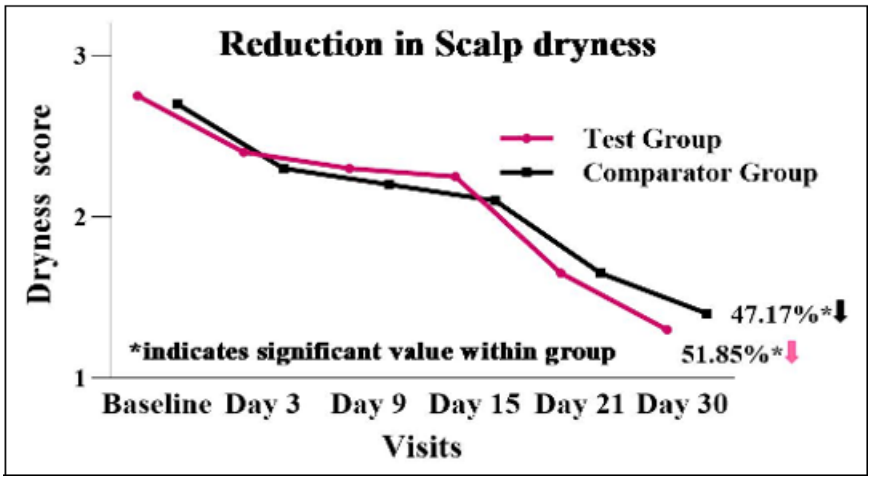


Figure 6: Reduction in scalp dryness

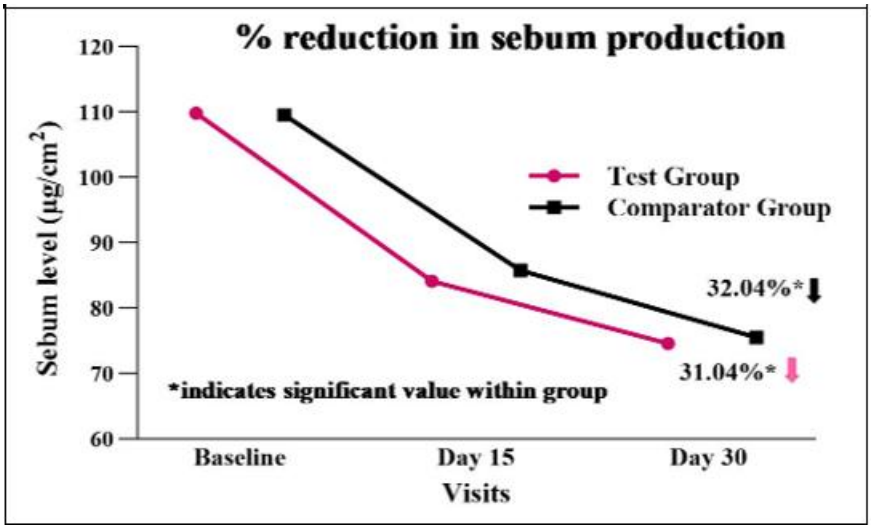


Figure 7: Reduction in sebum production

3.9 Assessment of participant perception of the efficacy of the product

To assess participants' subjective perceptions of the investigational product's efficacy and overall hair and scalp health, a 5-point scale questionnaire was used, ranging from 0 (very much worsened) to 4 (very much improved), with intermediate scores of 1 (worsened), 2 (neutral), and 3 (improved). The questionnaire evaluated various parameters, including scalp hydration, itchiness, redness, stickiness, cleanliness, hair smoothness, hair softness, dandruff content, scalp calmness, and ease of dry and wet hair combing. Responses were recorded throughout the study.

At baseline, the majority of participants in both groups reported scores between 0 and 2 (indicating worsened to no change) across most domains. However, by Day 30, there was a notable shift toward higher scores (3 or 4), reflecting perceived improvement.

For scalp hydration, at baseline, 65% of participants in both the test and comparator groups reported a score of 2 (no change). By Day 30, 55% of participants in the test group and 75% in the comparator group reported a score of 3 (improved). Similarly, improvement in perception was observed for itchiness was observed. Redness on the scalp improved in

65% of participants using the test product and 60% of those using the comparator (marketed) product.

Cleanliness perception improved markedly, with 60% of participants in the test group and 70% in the comparator group scoring 4 by Day 30. Hair smoothness and softness also showed positive changes by the end of the study.

Perception of dandruff reduction improved significantly in both groups, with 85% of participants in the test group and 90% in the comparator group reporting a score of 4. Other improvements, such as scalp calmness, dry hair combing, and wet hair combing followed a similar trend, with most participants reporting "improved" or "very much improved" scores by Day 30.

Overall, both products demonstrated positive shifts in user perception across all measured parameters, with the test group showing slightly better improved trends in certain domains such as redness, scalp calmness, and ease of combing, suggesting favourable tolerability and perceived efficacy. Data is represented in Figure 8.

Question	Test Group						Comparator Group				
	Baseline			Day 30			Baseline		Day 30		
Score	0	1	2	2	3	4	0	1	2	3	4
Does your scalp feel hydrated?	7 (35.00)	13 (65.00)	-	9 (45.00)	11 (55.00)	-	7 (35.00)	13 (65.00)	5 (25.00)	15 (75.00)	-
Do you notice the lack of itchiness on the scalp?	10 (50.00)	10 (50.00)	-	0 (0.00)	9 (45.00)	11 (55.00)	11 (55.00)	9 (45.00)	0 (0.00)	8 (40.00)	12 (60.00)
Do you feel a reduction in redness on the scalp?	5 (25.00)	11 (55.00)	-	0 (0.00)	13 (65.00)	7 (35.00)	5 (25.00)	11 (55.00)	8 (40.00)	12 (60.00)	-
Did you feel the product turned your hair sticky to the scalp?	2 (10.00)	13 (65.00)	-	1 (5.00)	12 (60.00)	7 (35.00)	5 (25.00)	11(55. 00)	6 (30.00)	12 (60.00)	2 (10.00)
Did you feel your scalp is clean?	1 (5.00)	16 (80.00)	-	-	7 (35.00)	13 (65.00)	1 (5.00)	10 (50.00)	-	6 (30.00)	14 (70.00)
Do you feel your hair is smoother?	0 (0.00)	9 (45.00)	-	3 (15.00)	15 (85.00)	-	-	6 (30.00)	6 (30.00)	14 (70.00)	-
Did you feel the decrease in dandruff content?	11 (55.00)	9 (45.00)	-	-	3 (15.00)	17 (85.00)	10 (50.00)	10 (50.00)	-	2 (10.00)	18 (90.00)
Do you feel the scalp calm?	-	11 (55.00)	-	1 (5.00)	8 (40.00)	11 (55.00)	2 (10.00)	11 (55.00)	-	11 (55.00)	9 (45.00)
Do you feel your hair soft?	-	10 (50.00)	10 (50.00)	2 (10.00)	15 (75.00)	3 (15.00)	-	7 (35.00)	6 (30.00)	14 (70.00)	-
Did you feel an improvement in dry hair combing?	2 (10.00)	12 (60.00)	6 (30.00)	3 (15.00)	16 (80.00)	1 (5.00)	2 (10.00)	9 (45.00)	4 (20.00)	16 (80.00)	-
Did you feel an improvement in wet hair combing?	2 (10.00)	13 (65.00)	5 (25.00)	3 (15.00)	14 (70.00)	3 (15.00)	3 (15.00)	11 (55.00)	3 (15.00)	15 (75.00)	2 (10.00)

Figure 8: Assessment of participant perception of the efficacy of the test and comparator products

Data is represented as a number of participants (% participants). Participants have given the score for each question asked based on their perception about product, the scoring was as follows The scale ranged from 0 (very much worsened) to 4 (very much improved), with intermediate points indicating worsening (1), neutral (2), and improved (3) states.

3.10 Assessment of vitals

There were no clinically significant changes observed in vital signs that is blood pressure, heart rate, body temperature, and respiratory rate throughout the study. All vital parameters remained within normal physiological ranges.

4. Discussion

This double-blind, randomized, parallel study investigated the clinical efficacy and safety of an anti-dandruff shampoo containing ScalpCleanse® with a marketed shampoo containing ketoconazole-zinc pyrithione for thirty days. There were 42 participants enrolled, with 22 in the test group and 20 in the comparator group and were observed for several qualitative and quantitative scalp measures including changes in dandruff scaling, scalp itching, dryness, erythema, sebum production, and tolerance. Several assessment points using standardized participant feedback, phototrichograms, and multifactor clinical scales were employed. For interventional comparison, both products were tested and evaluated through statistical analyses along with safety measures that included adverse event monitoring and compliance assessments.

This study is significant as it explores a plant-based formulation as a potential alternative to synthetic antifungal agents, responding to growing consumer demand for natural, well-tolerated scalp treatments without compromising efficacy. The study showed a gradual decrease in adherent and non-adherent dandruff, erythema, itching of the scalp, and dryness in both groups over a period of 30 days. Moderate scaling was observed at baseline that gradually and significantly improved from Day 9 onwards, with no cases of moderate or severe dandruff by Day 30. At baseline, the majority of participants showed moderate to severe erythema, which significantly decreased by Day 30. Likewise, scalp itching, which was initially noted as severe in most cases, demonstrated consistent improvement in both groups starting from Day 3, with all severe itching resolved by Day 15 which was continued till the end of the study. Phototrichogram analysis confirmed visible scalp improvement. Both shampoos showed comparable efficacy in reducing dandruff. Dryness of the scalp also showed gradual and significant improvement, with neither group facing severe dryness by Day 30, though improvement in the test group was greater than comparator group. Sebum production was reduced significantly after 15 days of use in both groups, with slightly higher improvement in the test group. Tolerance evaluations indicated that both shampoos were well-accepted, with no major adverse effects noted. In-use assessments, which included scalp sensitivity and tolerability reported by participants, showed similar safety profiles for both the tested and marketed products, augmenting the clinical effectiveness and safety of both formulations.

The incorporation of rosemary, burdock, Sappan wood extracts in the formulation is supported by both traditional usage and recent scientific evidence, particularly for conditions such as dandruff, erythema, sebum imbalance, and scalp itching. Rosemary extract has demonstrated clinical efficacy in reducing both adherent and non-adherent dandruff [8] and exhibits potent anti-inflammatory, antimicrobial, and antioxidant properties, which help regulate sebum production, reduce erythema, and restore scalp microbiota by targeting *Malassezia* and *Trichophyton* species [9]. Burdock extract (*Arctium lappa L.*), traditionally used for seborrheic conditions, possesses anti-inflammatory and antimicrobial activity, supporting its role in relieving itching, erythema, and oily scalp conditions [10].

Sappan wood (*Caesalpinia sappan*) offers anti-inflammatory, antioxidant, and antibacterial effects. Topical application has been shown to promote collagen deposition, angiogenesis, and reduce inflammatory cell infiltration, indicating improved scalp barrier repair and erythema reduction [11]. *Saussurea lappa* (Kuth root) has demonstrated strong anti-inflammatory, antimicrobial, and antioxidant properties, with evidence supporting its effectiveness against microbial overgrowth and in alleviating dandruff, erythema, and scalp irritation [12-13].

Previously conducted studies indicated that *Caesalpinia sappan* (C. sappan) has potent antifungal activity and is useful against *Malassezia*, this study also reported *Caesalpinia sappan* to have anti-inflammatory and antioxidant activity [14]. Preclinical studies conducted to evaluate the antimicrobial effect of *Caesalpinia sappan* reported that methanolic and ethyl acetate extracts of *C. sappan* exhibit strong antifungal activity against *Candida* species and *Aspergillus* strains, both of which are implicated in scalp disorders, including dandruff. The ability of *C. sappan* to inhibit fungal growth, particularly *Candida krusei*, *C. tropicalis*, and *Aspergillus niger* [15-16]. This suggests its role of as an active ingredient in shampoo containing ScalpCleanse® helping to reduce dandruff content, itching, and dryness as seen in the results of the current study.

Saussurea lappa has also demonstrated potent antifungal and antioxidant activity in in-vitro studies. An in-vitro study reported to have antifungal activity against *Candida* species and having potent free radical scavenging activity [17]. A polyherbal formulation containing *Saussurea lappa* has shown notable effectiveness in dandruff control, consistent with the results of the current study. Ayurvedic remedies, historically applied according to ailment intensity and resource availability, can face constraints because of intricate preparation techniques. Nonetheless, comparative clinical studies have demonstrated that this polyherbal formulation is more successful in reducing itching and skin cracking compared to Ketoconazole shampoo. Significantly, the use of Ketoconazole shampoo was linked to inflammation and itching, while multi-herbal solutions offered a soothing effect and anti-inflammatory advantages, rendering them a more favourable option for controlling dandruff. These results strengthen the possibility of using plant-based products to effectively tackle scalp issues [18].

The results of our research are consistent with those of an earlier study assessing 5% rosemary extract lotion and 2% ketoconazole lotion for scalp seborrheic dermatitis. Just as rosemary extract showed effectiveness akin to ketoconazole in decreasing dandruff severity and itching, our research revealed that the anti-dandruff shampoo containing ScalpCleanse® showed results comparable to the commercially available ketoconazole and zinc pyrithione shampoo. Both treatments successfully minimized erythema, scalp itching, and dryness while enhancing overall scalp health, showing no substantial difference in effectiveness between the two groups. These similar results emphasize the significance of plant-derived formulations as effective substitutes for traditional antifungal therapies [19].

A randomized, double-blind study was conducted to evaluate efficacy of 2% ketoconazole lotion and rosemary extract lotion in treating seborrheic dermatitis of the scalp. This study included 42 participants and was conducted for over two months. The Adherent Scalp Flaking Score (ASFS) was used to gauge the degree of dandruff, while the Dermatology Life Quality Index (DLQI) and Itchy Quant were used to gauge itching and quality of life, respectively. The results indicated that after one and two months, rosemary lotion significantly reduced itching symptoms ($P < 0.001$), while ketoconazole lotion was more successful in lowering the severity of dandruff ($P = 0.011$). Improvements in quality of life did not significantly differ between the two groups [20]. Similarly, current study has also reported to reduce itching, and adherent flaking significantly. These evidence suggest role of one of the ingredients of ScalpCleanse® in result.

A recent publication on *Arctium lappa* (Burdock) Root emphasized its antibacterial, antifungal, and anti-

inflammatory benefits, indicating its promise for scalp health. These characteristics correspond with our study results, where the active compounds in Burdock root, like inulin and tannins, aided in reducing dandruff by regulating *Malassezia*, calming scalp inflammation, and preserving microbial balance. Its dual role in promoting hair growth and reducing dandruff further enhances its therapeutic significance in anti-dandruff products [21].

A study evaluating the efficacy of 1% and 2% ketoconazole (KET) shampoo in severe dandruff and seborrheic dermatitis demonstrated that while KET 2% was significantly superior to KET 1% in reducing flakiness, *Malassezia* density, and overall dandruff severity, relapses still occurred during follow-up, highlighting limitations in long-term efficacy [22]. In contrast, herbal formulations, such as the shampoo containing ScalpCleanse® in our study, offer a broader therapeutic approach, leveraging antifungal, anti-inflammatory, and scalp-nourishing properties of botanical extracts. Taken together, these findings point to the potential of multi-herbal solutions as sustainable alternatives dandruff management compared to synthetic antifungal shampoo.

This study has demonstrated efficacy of Anti – Dandruff shampoo containing ScalpCleanse® in comparison to comparator shampoo in reducing dandruff content and reducing itching, dryness, erythema, sebum production. Results suggests Anti – Dandruff shampoo containing ScalpCleanse® to be equally effective in reducing dandruff content, itching, dryness, erythema, and sebum production as comparator shampoo with no serious side effects and adverse drug reactions (ADRs).

Future studies ought to lengthen the study period past one month and involve a broader, more varied group of participants to verify the lasting effectiveness of the shampoo containing ScalpCleanse®.

5. Conclusion

The research illustrates that the formulated Anti – Dandruff shampoo containing ScalpCleanse® is equally effective in the treatment of dandruff and seborrheic dermatitis as comparator shampoo with no side effects and serious ADRs. This product contains potent ingredients like Sappan Wood, Kushta, Burdock root, and Rosemary extracts, the formulation was endowed with significant antifungal, anti-inflammatory, and scalp-nourishing activities. Compared to the irritation caused by marketed shampoo and the possible relapse in conditions post-treatment with marketed shampoo, the herbal formulation provided sustained relief from dandruff and improved scalp health without the side effects. The actions of these plant-based extracts work synergistically to give a holistic approach to treating dandruff against the overgrowth of *Malassezia*, soothing inflammation, and providing hydration to the scalp.

Although this study did re-emphasize the formulation's promising potential, the small sample size and short duration of the study warrant long-term clinical trials with larger populations. Future studies may include mechanistic pathways, further studies on therapeutic effectiveness, and comparison with other antifungal agents. Findings do support the conclusion that the inclusion of ingredients may be a safer and more effective alternative for managing dandruff.

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All authors are part of Amvigor Organics Pvt. Ltd.

Funding Declaration
The material and testing expenses of the study were borne by Amvigor Organics Pvt. Ltd.

Informed Consent
Informed consent was obtained from all participants before enrolment.

Data Availability
The datasets generated and/or analyzed during the current study are not publicly available due to intellectual property constraints but are available from the corresponding author on reasonable request.

References

[1] Manuel F, Ranganathan S. A new postulate on two stages of dandruff: a clinical perspective. Int J Trichology. 2011;3(1):3–6.
[2] Keragala R, Kasunsiri TD, Kempitiya KS, Kumarapeli NN, Kumara K, Gunathilaka SS. A study on the extent, aetiology and associated factors of dandruff in a group of medical students and the in vitro effects of antidandruff preparations. Sri Lankan J Infect Dis. 2020;10(2):134.
[3] Ranganathan S, Mukhopadhyay T. Dandruff: The most commercially exploited skin disease. Indian J Dermatol. 2010;55(2):130–4. doi:10.4103/0019-5154.62734. PMID: 20606879; PMCID: PMC2887514.
[4] Shokeen D. The best natural fixes for dandruff, according to a dermatologist. Prevention. 2023.
[5] Mustarichie R, Rostinawati T, Pitaloka DAE, Saptarini NM, Iskandar Y. Herbal therapy for the treatment of seborrhea dermatitis. Clin Cosmet Investig Dermatol. 2022;15:2391–405.
[6] Filatov VA, Kulyak OY, Kalenikova EI. Chemical composition and antimicrobial potential of a plant-based substance for the treatment of seborrheic dermatitis. Pharmaceuticals (Basel). 2023;16(3):328. doi:10.3390/ph16030328. PMID: 36986428; PMCID: PMC10053605.
[7] Karnavat DR, Bhadane PS, Khairnar RM, Gavit SS. Formulation and evaluation of herbal antidandruff shampoo. Res J Pharmacogn Phytochem. 2022;14(3):179–84. doi:10.52711/0975-4385.2022.00032.

[8] Sadati MS, Fateme Alesana, Hekmat M, Parvizi MM. Efficacy of Topical Rosemary Extract Lotion Versus Topical 2% Ketoconazole Lotion in the Treatment of Seborrheic Dermatitis: A Double Blind Randomized Controlled Clinical Trial. Dermatology Practical & Conceptual. 2024 Oct 30;14(4):e2024242–2.
[9] Hashem MM, Attia D, Hashem YA, Hendy MS, AbdelBasset S, Adel F, et al. Rosemary and neem: an insight into their combined anti-dandruff and anti-hair loss efficacy. Scientific Reports [Internet]. 2024 Apr 2;14(1):7780. Available from: https://www.nature.com/articles/s41598-024-57838-w
[10] Miazga-Karska M, Michalak K, Ginalska G. Anti-Acne Action of Peptides Isolated from Burdock Root-Preliminary Studies and Pilot Testing. Molecules (Basel, Switzerland) [Internet]. 2020 Apr 27;25(9). Available from: https://pubmed.ncbi.nlm.nih.gov/32349230/
[11] Sucita R, Fikri F, Purnomo A, Maslamama S, Purnama M. The efficacy of topically applied Sappan wood (Caesalpinia sappan L.) ethanol extract during incision wound healing in albino rats. Open Veterinary Journal [Internet]. 2024 [cited 2025 May 9];14(7):1561. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC11338603/
[12] Chang KM, Choi SI, Kim GH. Anti-oxidant Activity of Saussurea lappa C.B. Clarke Roots. Preventive Nutrition and Food Science. 2012 Dec 31;17(4):306–9.
[13] Elnour AAM, Abdurahman NH. Current and potential future biological uses of Saussurea costus (Falc.) Lipsch: A comprehensive review. Heliyon. 2024 Sep;10(18):e37790.
[14] Hwang MK, Lee YH, Kim DC. Antimicrobial activity of Caesalpinia sappan L. extract against skin flora. J Appl Biol Chem. 2021;64(1):83–7.
[15] Mohan G, Anand SP, Doss A. Efficacy of aqueous and methanol extracts of Caesalpinia sappan L. and Mimosa pudica L. for their potential antimicrobial activity. South Asian J Biol Sci. 2011;1(2):48–57.
[16] Kekuda TRP, Vinayaka K, Raghavendra HL. Caesalpinia sappan L. (Caesalpiniaceae): A review on its phytochemistry and pharmacological activities. In: Medicinal and Aromatic Plants: Traditional Uses, Phytochemistry and Pharmacological Potential. 2021 Feb.
[17] Alnahdi HS, Danial EN, Elhalwagy MEAE, Ayaz NO. Phytochemical studies, antioxidant properties, and antimicrobial activities of herbal medicinal plants Costus and Cidir used in Saudi Arabia. Int J Pharmacol. 2017;13(5):481–7.
[18] Madan P, Rathi B, Dhote S, Wairagade S, Gadgil SS, Joshi SM. An Ayurvedic approach in the management of Darunak (Dandruff) – A review. Nat Volat Essent Oils. 2021;8(5):1315–20.
[19] Sadati MS, Alesana F, Hekmat M, Parvizi MM. Efficacy of topical rosemary extract lotion versus topical 2% ketoconazole lotion in the treatment of seborrheic dermatitis: a double-blind randomized controlled clinical trial. Dermatol Pract Concept. 2024;14(4):e2024242.
[20] Hashem MM, Attia D, Hashem YA, Hendy MS, AbdelBasset S, Adel F, et al. Rosemary and neem: an insight into their combined anti-dandruff and anti-hair loss efficacy. Sci Rep. 2024;14:7780.
[21] Harnessing the power of Arctium lappa root: a review of its pharmacological properties and therapeutic applications. Sci Rep. 2024;14(49).
[22] Pierard-Franchimont C, Goffin V, Decroix J, Pierard GE. A multicenter randomized trial comparing the antidandruff efficacy of 1% and 2% ketoconazole shampoos. Skin Pharmacol Appl Skin Physiol. 2002;15(6):434–41.

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