

Clinical evaluation of the efficacy and safety of 'ThriveCo anti-dandruff pre-shampoo treatment,' containing Zenscalpin™ in the management of scalp dandruff in healthy adults

Abstract

Introduction: Dandruff, a common scalp disorder often linked to *Malassezia* overgrowth, is characterized by flaking, itching, and irritation due to inflammation and compromised scalp barrier function. Conventional treatments focus on antifungal, anti-inflammatory, and keratolytic approaches. ThriveCo Anti-Dandruff Pre-Shampoo Treatment, powered with Zenscalpin™ (a unique blend of witch hazel, piroctone olamine, and niacinamide) designed to address dandruff by targeting reduction in fungal overgrowth, inflammation, and scalp skin barrier repair. This study evaluates the safety, efficacy, and tolerability of the scalp serum for its immediate effectiveness in managing dandruff in healthy adults.

Methods: This prospective, interventional, open-label, single-center, single-arm clinical study was conducted to evaluate the efficacy of an anti-dandruff serum for dandruff management. Ethical approval was obtained from the ACEAS Independent Ethics Committee, and written informed consent was obtained from all participants prior to any clinical procedures. The severity of dandruff and seborrheic dermatitis was assessed using the Adherent Scalp Flaking Score (ASFS), along with dermatological evaluations and phototrichogram analysis using the CASLite Nova Instrument. Statistical analysis was performed using SPSS (v29.0.1.0) and Microsoft Excel 2019, with a significance level set at 5%. A total of 32 individuals were enrolled and 28 healthy adult participants aged 18–60 years completed the study, with the primary focus on assessing improvements in scalp health at 30 minutes post-application on Day 1 and following 8 days of serum use.

Results: The study demonstrated significant improvements in scalp health following 8 days of using the test hair serum. In comparison to the baseline, a 27.72% reduction in adherent scalp flaking was observed within 30 minutes of application on Day 1. This effect further increased to a 54.79% reduction by Day 8. These results were statistically significant, with a p-value of <0.0001, indicating the serum's effectiveness in alleviating dandruff. Additionally, 92.86% of subjects reported reduced scalp dryness by Day 8, and a significant reduction in skin itchiness was observed, with 92.86% of subjects experiencing no itchiness by the end of the study. Reductions in scalp redness, roughness, and scaliness were also noted, with 96.43% of participants reporting no redness or scaliness by Day 8. The serum effectively improved overall scalp health, with most participants reporting smoother scalp texture and reduced discomfort, supporting its potential for daily use in dandruff management. No adverse events were reported throughout the study.

Conclusion: The Test Anti-Dandruff Serum, enriched with Zenscalpin™ containing witch hazel, piroctone olamine, and niacinamide, demonstrated significant efficacy in reducing dandruff and enhancing scalp health within 8 days. By targeting fungal overgrowth, inflammation, and skin hydration, it effectively reduced flaking, dryness, itchiness, redness, and scaliness. These results highlight its potential as a clinically effective adjuvant therapy and a reliable option for daily dandruff management.

Keywords: scalp dandruff, healthy adults, seborrheic dermatitis, piroctone olamine, 'ThriveCo anti-dandruff pre-shampoo treatment'

Volume 8 Issue 4 - 2024

Maheshvari Patel,^{1,2} Nayan Patel,³ Apeksha Merja,⁴ Saurav Patnaik⁵¹PhD Scholar (Clinical Pharmacology), Swaminarayan University, Kalol, India²Chief Operating Officer and Founder, NovoBliss Research Private Limited. 313, Gujarat, India³Medical Director, NovoBliss Research Private Limited. 313, Gujarat, India⁴Sub-Investigator, NovoBliss Research Private Limited. 313, Ahmedabad, India⁵Director, Anveya Living Private Limited, OLD SY No. 91/3, New SY No. 91/10, Karnataka, India

Correspondence: Maheshvari Patel, NovoBliss Research Private Limited. 313, Silver Radiance-4, S.G. Highway, Near Bhavik Publications, Gota, Ahmedabad - 382481, Gujarat, India, Tel +91 99090 13236, Email maheshvari@novobliss.in

Received: December 06, 2024 | **Published:** December 19, 2024

Introduction

Dandruff, clinically known as seborrheic dermatitis, is a common scalp disorder characterized by the shedding of white flakes of dead skin. It affects a large proportion of the population globally, leading to discomfort, scalp itching, and embarrassment due to visible flaking.¹ The pathophysiology of dandruff involves an imbalance between scalp sebum production and the proliferation of *Malassezia* species, particularly *Malassezia globosa*.² This yeast metabolizes scalp lipids,

producing irritant by-products like oleic acid, which compromise the scalp barrier function and lead to inflammation.³ The immune response to these irritants causes scalp irritation, pruritus, and increased keratinocyte turnover, manifesting as dandruff.⁴

Treatment strategies for dandruff aim to address the overgrowth of *Malassezia*, reduce inflammation, and normalize scalp barrier function.⁵ Commonly used treatments include antifungal agents, such as ketoconazole, zinc pyrithione, and selenium sulfide, which

target *Malassezia* species.⁶ Salicylic acid, a keratolytic agent, helps in exfoliating scalp buildup.⁷ Corticosteroids may be prescribed in severe cases to reduce inflammation.⁸

Recent studies have explored safer, more effective treatments for dandruff, focusing on botanical and novel antifungal ingredients.⁹ Clinical trials show that combining antifungal, anti-inflammatory, and keratolytic agents provides better outcomes than single treatments.¹⁰ However, long-term control often requires a combination of therapeutic and cosmetic products.¹¹

The test treatment is a novel formulation aimed at addressing scalp dandruff with active ingredients such as witch hazel, piroctone olamine, and niacinamide, each selected for their targeted benefits in managing scalp health. Witch hazel helps reduce inflammation and soothe irritation, while piroctone olamine combats fungal overgrowth, specifically addressing dandruff caused by *Malassezia* species. Niacinamide supports scalp barrier integrity, reducing dryness and promoting hydration. Together, these ingredients provide a comprehensive approach to scalp care and dandruff control.¹²

Witch hazel (*Hamamelis virginiana*) is an astringent with anti-inflammatory and soothing properties.¹³ It reduces scalp irritation and oil production, limiting *Malassezia* growth.¹⁴ Its astringent nature tightens scalp pores, and its anti-inflammatory action helps reduce redness and itching.¹⁵

Piroctone olamine is a synthetic antifungal agent that targets *Malassezia* species, disrupting fungal cell membranes.¹⁶ It effectively reduces dandruff symptoms like flaking and itching and has fewer side effects than older antifungals.¹⁷ It also helps restore the natural scalp balance.¹⁸

Niacinamide (vitamin B3) is a multifunctional agent with anti-inflammatory and sebum-regulating effects.¹⁹ It reduces inflammation, enhances scalp barrier function, and regulates sebum production, limiting fungal growth.²⁰ Niacinamide also protects the scalp from environmental stressors.²¹

This interventional study evaluated the clinical safety, efficacy, and in-use tolerability of test Anti-dandruff Serum in healthy adult subjects with dandruff, aiming to provide evidence supporting its effectiveness as a dandruff treatment. The study focused on assessing its therapeutic benefits while ensuring minimal side effects, addressing the growing need for an effective solution to manage dandruff and improve scalp health

Materials and methods

Ethical conduct of the study

This study was conducted in full compliance with the New Drugs and Clinical Trials Rules 2019, the ICH E6 (R2) guideline on Good Clinical Practice, the ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), and the Declaration of Helsinki (Brazil, October 2013). Ethical approval for the study protocol was obtained from the Ethics Committee prior to initiating any study-related procedures. Informed consent was obtained from all participants before their enrolment, following a comprehensive explanation of the study's objectives, procedures, confidentiality protocols, and the voluntary nature of their participation.

Additionally, this clinical study was registered with the Clinical Trial Registry of India (CTRI) under the identifier CTRI/2023/12/060424.

The study protocol received approval from the ACEAS Independent Ethics Committee, prior to the commencement of any study activities. This robust ethical framework ensures the study's adherence to both international and national ethical standards, prioritizing the protection of the rights, safety, and well-being of all participants.

Study design

This prospective, interventional, open-label, single-center, single-arm clinical study was conducted to evaluate the safety, efficacy, and in-use tolerability of the test scalp hair serum used for 8 days. The study was conducted at NovoBliss Research Private Limited, a Contract Research Organization in Ahmedabad, India. A total of 32 healthy adult male and female subjects aged 18 to 60 years with scalp dandruff were enrolled, of whom 28 completed the study. Subject recruitment commenced on January 11, 2024, with the first subject's visit, and was completed on February 8, 2024, with the last subject's final visit.

The primary objective of this study was to evaluate the effectiveness of the test treatment by measuring the change in adherent scalp flaking scores from baseline, both before and after the treatment. Secondary objectives included assessing the effectiveness of the test treatment in terms of changes in scalp appearance, specifically regarding itchiness, redness, roughness, and scaliness, from baseline to after treatment use. Additionally, the study evaluated changes in visible scalp flakes through phototrichogram analysis using CASLite Nova instrument before and after the treatment. Lastly, the perception of the treatment's effectiveness was also assessed by comparing participants' feedback before and after using the test treatment.

The study population was carefully selected based on predefined inclusion and exclusion criteria to ensure consistency and uniformity. Eligible participants were required to meet the following inclusion criteria: they were aged 18 to 60 years at the time of consent, and both healthy males and non-pregnant, non-lactating females were considered. Females of childbearing potential were required to have a self-reported negative urine pregnancy test. Participants were required to be in generally good health, as determined by recent medical history, and have a mild to moderate dandruff condition, assessed using the Adherent Scalp Flaking Score (ASFS) during screening. Additionally, eligible participants had to have an unwashed and untreated scalp for at least five days prior to screening. Furthermore, all subjects needed to demonstrate the willingness and ability to follow the study protocol, attend all scheduled visits, and provide written informed consent after understanding the study requirements.

The exclusion criteria were evaluated to ensure the applicability of the study outcomes by excluding individuals whose conditions or treatments could interfere with the results. Participants were excluded if they had known allergies to any ingredients in the test treatment, a history of scalp dermatological conditions other than dandruff, or had used alcohol, drugs, or other dandruff-control products during the study. Individuals with scalp irritation, open wounds, or concurrent skin conditions, as well as those who had used systemic corticosteroids, antibiotics, immunosuppressants, or topical steroids within the past 30 days, were also excluded. Additionally, participants with a history of laser therapies, chemical peels, excessive sun exposure, or recent use of retinoids, those planning to shave their scalp, or those who were pregnant or breastfeeding were not eligible. Subjects with any medical condition or medication use that could pose a risk, as well as those participating in other clinical trials, were also excluded from the study.

Study procedure

The study was conducted over two scheduled visits, with assessments performed before and after the usage of the test treatment to evaluate its efficacy. Visit 01 (Day 01) included participant screening, enrolment, initiation of the test treatment usage period, the first post-usage wash, and baseline evaluations. Visit 02, scheduled for Day 08 (+2 Days), involved a detailed scalp evaluation and marked the end of the study. Details about the test treatment for hair growth and grey hair management are provided in Table 1.

Table 1 Details about the test treatment

Type of treatment	Anti-dandruff scalp hair serum
Name of treatment	ThriveCo Anti-Dandruff Pre-Shampoo Treatment
Marketed and manufactured by	Anveya Living Private Limited
Mode of usage	Apply the ThriveCo anti-dandruff pre-shampoo treatment to the scalp using the dropper, massaging it in a circular motion, and leave it on for 5 minutes. Afterward, wet your hair and thoroughly cleanse it with ThriveCo Hair Vitalizing Rosemary Shampoo.
Active ingredients	(Zenscalpin™) Witch Hazel, Piroctone Olamine, and Niacinamide.
Route of administration	Topical Application
Frequency	Thrice in a week ThriveCo Hair Vitalizing Rosemary Shampoo was provided along with the ThriveCo Anti-dandruff Serum to maintain uniformity among the participants.
*Note	

Efficacy assessments, including ASFS scoring, changes in scalp appearance, visual dandruff assessment through photographs, and the subject's feedback on the effectiveness of the test treatment, were conducted on Day 01 prior to test treatment usage and at T30 minutes post-usage. Further assessments were repeated on Day 08 (+2 Days) to monitor treatment outcomes.

A clinical and physical examination of the participants was conducted by a study dermatologist, who assessed the general appearance of the scalp, including parameters such as dryness, itchiness, redness, roughness, scaliness, and smoothness, to evaluate the overall scalp. These assessments were performed prior to the application of the test treatment on Day 01 and subsequently at 30 minutes (T30 mins) after treatment on Day 01 and on Day 08. Furthermore, the Adherent Scalp Flaking Score (ASFS) was evaluated to quantify the severity of dandruff. The scalp was divided into eight zones, and each zone was assessed for adherent dandruff flakes using a 0–10 scale, excluding loose flakes in the hair. The total ASFS was calculated by summing the scores from all eight zones, yielding a range of 0–80. The scores were categorized as mild (16–24), moderate (25–34), or severe (35–80) for representation purposes. ASFS evaluations were performed before the test treatment on Day 01 and after treatment at T30 minutes on Day 01 and on Day 08, ensuring comprehensive monitoring of scalp conditions and treatment outcomes.

The CASLite Nova Hair Analysis System (CATSEYE SYSTEMS & SOLUTIONS PVT LTD, INDIA) served as a non-invasive and reproducible method, relying on manual marking of selected scalp

areas on close-up images of the target regions. A skin marker was used to standardize the assessment location, ensuring consistency, and the same site was photographed using the instrument. Scalp condition was assessed by the study staff utilizing the CASLite Nova system, focusing on the 1x1 cm central vertex area of the scalp. Evaluations of the test treatment's effects were conducted on Day 01 before treatment application and post-treatment at T30 minutes on Day 01, as well as on Day 08 (Figure 1).



Figure 1 CASLite Nova.

Statistical analysis

Descriptive statistics were used to summarize continuous variables, including the sample size (N), mean, standard deviation (SD), median, and the minimum and maximum values. Categorical variables were reported as frequencies and percentages, with visual representations provided when appropriate. Statistical analyses were performed using SPSS software (Version 29.0.1.0) and Microsoft® Excel 2019, with a 5% significance level applied. Subjects who withdrew from the study were excluded from the statistical evaluation.

Data handling and analysis

All data were carefully reviewed and cleaned before analysis to ensure accuracy and completeness by quality control and quality assurance department of NovoBliss Research. Frequency analyses and cross-tabulations were performed to ensure data accuracy and consistency. Missing data were addressed through appropriate imputation methods or excluded from the analysis, depending on the extent and nature of the missingness. The results of the statistical tests evaluated by the paired t-test, including p-values, were reported with corresponding confidence intervals to provide a measure of precision and reliability.

Sample size determination

A sample size calculation was conducted to ensure adequate power for detecting clinically meaningful differences. Based on this calculation, 32 subjects were enrolled to ensure that 28 subjects would complete the study.

Results

Demographic and other baseline characteristics

A total of 32 subjects were enrolled in the study, with 28 subjects successfully completing all scheduled visits. Only those subjects who completed the full course of visits were included in the statistical analysis to ensure the integrity of the data. The study cohort consisted of 53.13% female and 46.88% male participants, ensuring a balanced representation of both genders. The average age of the participants was 37.06 years, reflecting a diverse group within the adult age range. The study maintained high compliance with both the intervention and assessment schedules, with participants adhering to the prescribed

protocols throughout the study period. This ensured that the data collected was reliable and robust for statistical analysis. Additionally, the mean height was 157.19 cm, and the mean weight was 59.09 kg (Figure 2).

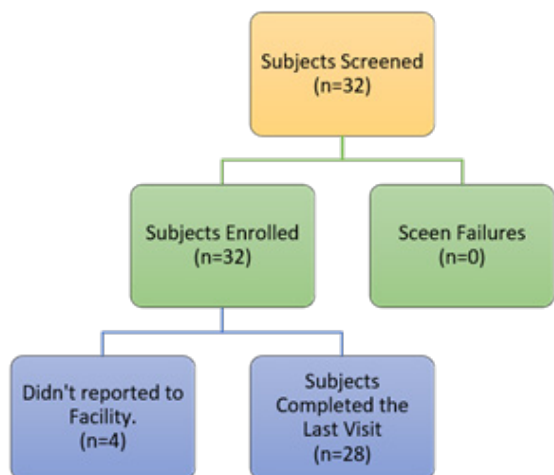


Figure 2 Subject Disposition.

Primary endpoints

Adherent scalp flaking score using ASFS scoring scale

Reduction in adherent scalp flaking was observed throughout the study, demonstrating a statistically significant improvement. Results indicated a 27.72% decrease in the adherent scalp flaking mean value, with a baseline mean of 31.21 ± 2.57 , which reduced to 22.50 ± 3.11 at T30 mins on Day 01, and further to 14.07 ± 5.06 by Day 08, with a highly significant p-value of <0.0001 . This reduction continued over the 8-day treatment period, with a 54.79% decrease observed by Day 08. These findings underscore the substantial efficacy of the test treatment in significantly reducing scalp dandruff, with improvements sustained throughout the treatment period, as reflected by the adherent scalp flaking score (ASFS) (Figure 3).

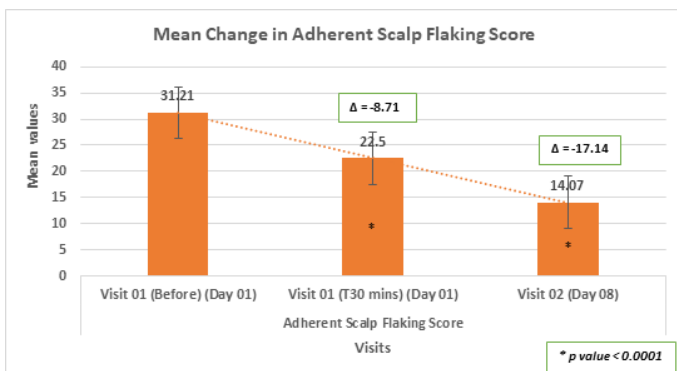


Figure 3 Mean change in adherent scalp flaking score across visits.

Previous studies have shown that witch hazel, piroctone olamine, and niacinamide are effective in reducing scalp flaking. Witch hazel soothes the scalp, piroctone olamine targets the Malassezia fungus, and niacinamide improves skin barrier function and reduces inflammation. In the current study, the test product containing these ingredients led to a 27.72% reduction in adherent scalp flaking after 30 minutes and a 54.79% reduction by Day 08, demonstrating continuous effectiveness.

The adherent scalp flaking score (ASFS) showed a significant decrease from 31.21 ± 2.57 at baseline to 22.50 ± 3.11 at T30 min on Day 01, and 14.07 ± 5.06 by Day 08, with a p-value of <0.0001 . These

results support the previous literature, confirming the efficacy of witch hazel, piroctone olamine, and niacinamide in reducing dandruff and improving scalp health over an 8-day treatment period.

Secondary endpoints

General appearance of the scalp (Figure 4)

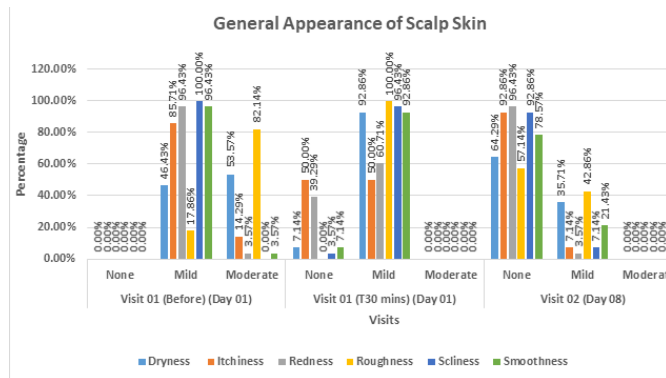


Figure 4 General appearance of scalp skin.

Scalp dryness: Baseline data showed 53.57% of subjects had moderate dryness, and 46.43% had mild dryness. After 30 minutes, 92.86% reported mild dryness, and 7.14% had no dryness. By Day 8, 64.29% had no dryness, with 35.71% reporting mild dryness, indicating significant improvement in skin hydration.

Skin itchiness: Initially, 14.29% had moderate itchiness, and 85.71% had mild itchiness. After 30 minutes, 50% had no itchiness, and 50% had mild itchiness. By Day 8, 92.86% reported no itchiness, with only 7.14% experiencing mild itchiness, demonstrating effective alleviation of itchiness.

Skin redness: Baseline data showed 96.43% had mild redness, and 3.57% had moderate redness. After 30 minutes, 39.29% had no redness, and 60.71% had mild redness. By Day 8, 96.43% had no redness, with 3.57% reporting mild redness, reflecting a significant reduction.

Skin roughness: At baseline, 82.14% had moderate roughness, and 17.86% had mild roughness. After 30 minutes, 100% had no roughness. By Day 8, 57.14% had no roughness, and 42.86% reported mild roughness, showing continuous improvement in texture.

Skin scaliness: All subjects had mild scaliness at baseline. After 30 minutes, 96.43% had mild scaliness, and 3.57% had none. By Day 8, 92.86% had no scaliness, and 7.14% had mild scaliness, indicating a significant reduction in scaliness.

Skin smoothness: Baseline data showed 96.43% had mild smoothness, and 3.57% had moderate smoothness. After 30 minutes, most subjects had mild smoothness. By Day 8, 67.86% had mild smoothness, and 32.14% reported moderate smoothness, indicating an improvement in skin smoothness over time.

Evaluation of visible flake reduction with CASLite Nova using Phototrichogram

The assessment of visible flakes across scalp zones demonstrated significant improvement in scalp health following treatment with Test Anti-dandruff Serum over 8 days. At baseline, most participants (96.43%) exhibited dry scalp with much keratin, which decreased markedly after 30 minutes of application to 03.57% participants and on Day 8 the end of the study, 28.57% subjects have normal scalp with good condition hair thickness and density and 67.86%

subjects had dry scalp with some keratin. These results highlight the serum's efficacy in reducing keratin buildup, alleviating dandruff, and enhancing overall scalp and hair health (Figure 5).



Figure 5 Scalp dandruff evaluation using CASLite Nova.

Consumer perception

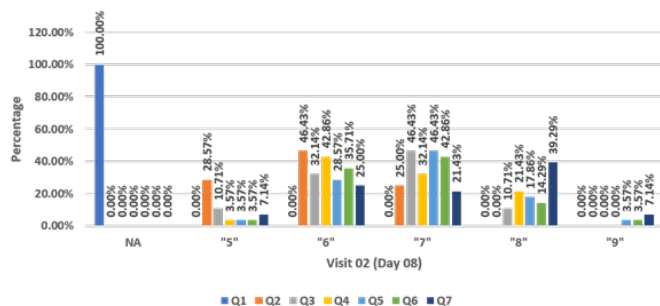


Figure 6 Treatment perception questionnaire.

The following 9-point hedonic scale evaluates the effectiveness of the test treatment in various aspects. First, respondents are asked to indicate the name of the earlier product they used. Then, on a scale of 1-9, participants will rank the effectiveness of the test treatment in several areas: reduction in skin dryness, itchiness, redness, roughness, scaliness, and smoothness (Q2); reduction in dandruff (Q3); the treatment's ability to combat dandruff and strengthen hair (Q4); providing clean and fresh hair/scalp (Q5); maintaining scalp hydration (Q6); and overall satisfaction with the test treatment (Q7). The ratings range from 1, indicating "extremely ineffective," to 9, indicating "extremely effective," with intermediate scores reflecting varying levels of effectiveness.

The study demonstrates the significant effectiveness of the test treatment compared to the previous scalp care products used by participants. Initially, 57.14% of subjects had prior experience with other scalp care products, while 42.86% had not used any. Among those who used an earlier product, 42.86% disagreed that it helped with scalp issues such as dryness, itchiness, redness, roughness, scaliness, and smoothness, with only 7.14% agreeing. After using the test treatment for 8 days, 71.43% of participants agreed it effectively reduced scalp dryness and improved overall skin condition. Regarding dandruff reduction, 39.29% found the earlier product ineffective, while only 10.71% agreed it helped. In contrast, 89.28% of subjects noted significant dandruff reduction with the test treatment. Additionally, 96.43% of participants agreed the test treatment not only reduced dandruff but also strengthened hair, provided clean and fresh scalp, and effectively hydrated the scalp, compared to the earlier product, with 96.43% agreeing on improved hydration.

In terms of overall satisfaction, only 21.43% of participants were satisfied with the earlier product, whereas 92.86% expressed satisfaction with the test treatment after 8 days, highlighting a clear preference. The test treatment demonstrated substantial superiority over the earlier product in areas like dandruff reduction, scalp hydration, cleanliness, and overall hair health. These findings suggest that the test treatment is an effective and well-tolerated solution for managing dandruff and promoting scalp health.

Discussion

Scalp dandruff, or pityriasis capitis, is a prevalent dermatological disorder marked by the shedding of skin cells from the scalp. It typically manifests as white or yellowish flakes, accompanied by itching and discomfort.²² Dandruff is a common scalp condition characterized by visible flaking, irritation, and itchiness, which can significantly affect both the physical and emotional well-being of individuals. The primary cause of dandruff is the overgrowth of *Malassezia*, a yeast that thrives on sebum produced by the scalp, triggering an inflammatory response. This leads to rapid turnover of skin cells, resulting in the scaling and flaking seen in dandruff. Other factors, such as changes in weather, stress, and underlying skin conditions, can also contribute to dandruff development. Despite the availability of various treatments, managing dandruff remains challenging, and there is a continual need for more effective and comprehensive treatments that address both the symptoms and the underlying causes of the condition.^{1,23}

Witch hazel (*Hamamelis virginiana*), known for its anti-inflammatory and astringent properties, has long been used to soothe scalp irritation, reduce redness, and control excess oil, promoting overall scalp health.²⁴ Piroctone olamine, a synthetic antifungal, targets *Malassezia* to reduce dandruff symptoms such as flaking and itching while restoring scalp balance with minimal side effects.¹⁷ Additionally, niacinamide (vitamin B3) provides anti-inflammatory, sebum-regulating, and barrier-enhancing benefits, controlling fungal growth and protecting the scalp from environmental stressors.¹⁹

Current therapeutic strategies for dandruff focus on addressing the overgrowth of *Malassezia*, reducing inflammation, and normalizing the scalp barrier. Antifungal agents, such as ketoconazole, zinc pyrithione, and selenium sulfide, are commonly used to target *Malassezia* and control scalp flaking. Keratolytic agents, such as salicylic acid, help in exfoliating excess scalp buildup, while corticosteroids may be prescribed for more severe cases to reduce inflammation. However, these treatments are not without limitations. Prolonged use of antifungal agents and corticosteroids may lead to scalp irritation or resistance, highlighting the need for alternative treatments that offer broad therapeutic effects without the potential for adverse outcomes.^{25,26}

In this study, the test treatment showed significant efficacy in improving various scalp conditions associated with dandruff. A marked reduction in scalp flaking was observed as early as 30 minutes after application, with further improvement noted over the 8-day treatment period. These findings demonstrate that the test treatment not only provides immediate relief but also offers long-term benefits for scalp health. Additionally, improvements were observed in scalp dryness, itchiness, redness, roughness, and scaliness, indicating that the treatment addresses multiple aspects of scalp health beyond just flaking.^{27,28} This highlights the potential of this treatment as a comprehensive solution to dandruff.

When compared to existing treatments, the results of this study align with previous research on the individual ingredients in the test treatment. Witch hazel is known for its anti-inflammatory properties,

which likely contributed to the observed reduction in scalp redness and itchiness.²⁹ Piroctone olamine, an antifungal agent, has been shown to be effective in targeting *Malassezia*, which is consistent with the reduction in scalp flaking observed in this study.²⁹ Niacinamide, a compound with known barrier-repairing and anti-inflammatory properties, likely played a key role in improving scalp dryness and overall texture.³⁰ The combination of these ingredients appears to offer a synergistic effect, providing a more holistic approach to dandruff treatment by addressing both the symptoms and the underlying causes.

In comparison to traditional dandruff therapies, such as ketoconazole and zinc pyrithione, which primarily target fungal overgrowth, the test treatment also provides significant anti-inflammatory and hydrating benefits. While antifungal agents may control the fungal aspect of dandruff, they often do not address the other symptoms, such as itching, redness, and dryness.³¹ This study suggests that the test treatment offers a more comprehensive solution by targeting multiple facets of dandruff, including inflammation, fungal overgrowth, and moisture balance, which may make it a more effective treatment option compared to standard therapies.

Supporting this notion, a similar clinical study evaluating a topical formulation combining piroctone olamine and zinc pyrithione for dandruff treatment found significant improvements in scalp flaking and pruritus within a week. The study emphasized the necessity of incorporating anti-inflammatory agents to address itching and redness, beyond the antifungal effects. This aligns with the findings from the present study, where the anti-inflammatory properties of witch hazel and niacinamide contributed to the reduction of scalp irritation and dryness.³² Moreover, another study investigated a scalp serum containing tea tree oil and salicylic acid for dandruff management, revealing reductions in scalp flaking, itchiness, and oiliness over 8 weeks. The serum also helped balance oil production and soothe irritation, which parallels the effects seen with the test treatment in this study. This supports the idea that a combination of antifungal and anti-inflammatory agents can provide a holistic approach to managing dandruff, improving scalp health, and addressing both fungal overgrowth and irritation.³³ Despite these promising results, the study has several limitations. The relatively small sample size limits the generalizability of the findings, and further research with a larger cohort would help confirm the broader applicability of these results. Additionally, the study duration of 8 days is relatively short, and longer-term studies are needed to evaluate the sustained efficacy and safety of the test treatment. The lack of a placebo or control group also limits the ability to definitively attribute the observed improvements to the test treatment itself. Future randomized controlled trials would be helpful in confirming the treatment's efficacy relative to other established dandruff therapies.³⁴

The future scope of this study lies in expanding research to evaluate the long-term safety and efficacy of Test Anti-dandruff Serum across diverse populations and varying severity of dandruff conditions. Future studies could explore its effectiveness in individuals with chronic or more severe dandruff, as well as in different age groups, skin types, and environmental conditions. Additionally, incorporating a placebo-controlled, double-blind design would help strengthen the evidence of the treatment's comparative effectiveness against existing dandruff therapies. Further investigations could also assess the serum's potential for managing other scalp conditions, such as seborrheic dermatitis or scalp psoriasis. Moreover, exploring the impact of extended use beyond the 8-day period could provide valuable insights into its sustained efficacy and overall dermatological benefits. Finally, conducting studies to assess the serum's compatibility with other hair care products and its potential to be used in combination with other

scalp treatments may broaden its clinical application in holistic hair and scalp health management.³⁵

Conclusion

The ThriveCo Anti-Dandruff Pre-Shampoo Treatment, formulated with Zenscalpin™ containing key ingredients such as witch hazel, piroctone olamine, and niacinamide, demonstrated significant clinical efficacy in managing dandruff and improving scalp health over an 8-day treatment period. These ingredients target the primary factors contributing to dandruff, including fungal overgrowth, inflammation, and compromised skin hydration. Witch hazel provides anti-inflammatory and astringent effects, piroctone olamine addresses *Malassezia* fungus, and niacinamide strengthens the skin barrier while regulating sebum production. The synergistic action of these components led to significant reductions in scalp flaking, dryness, itchiness, redness, roughness, and scaliness.

These findings, supported by statistically significant and clinically meaningful improvements, establish ThriveCo Anti-Dandruff Pre-Shampoo Treatment as an effective adjuvant therapy for dandruff management and a suitable option for regular use in daily hair care routines.

Acknowledgments

The authors extend their sincere gratitude to Dr. Nayan Patel, as Medical Director, and Dr. Maheshvari Patel, PhD Scholar, as Project Director, for their invaluable contributions. Appreciation is conveyed to Anveya Private Limited, along with their committed teams, for their collaborative support. We also thank the NovoBliss Research study team for overseeing the in-vivo clinical study, the statistical team for their expertise in data analysis, and the scientific writing team for their assistance in manuscript preparation. Special acknowledgment is to Shambhavi Srivastava for drafting this article. Heartfelt appreciation is expressed to all study participants for their significant and valuable contributions to the research endeavour.

Conflict of interest

In compliance with the ICMJE uniform disclosure requirements, all authors declare the following: No financial support was received from any organization for the submitted work. Maheshvari N Patel and Nayan K Patel are employed by NovoBliss Research Private Limited. Apeksha M Merja has received personal fees from NovoBliss Research Private Limited. Saurav Patnaik is employed by Anveya Private Limited. All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

Funding

Anveya Living Private Limited.

References

1. Schwartz JR, Messenger AG, Tosti A, et al. A comprehensive review of dandruff and seborrheic dermatitis—past, present and future. *J Clin Invest Dermatol*. 2013;1(1):10–17.
2. Warner RR, Schwartz JR, Boissy Y, et al. Dandruff has an altered stratum corneum ultrastructure that is improved with zinc pyrithione shampoo. *J Am Acad Dermatol*. 2001;45(6):897–903.
3. Ro BI, Dawson TL. The role of sebaceous gland activity and scalp microfloral metabolism in the etiology of seborrheic dermatitis and dandruff. *J Invest Dermatol Symp Proc*. 2005;10(3):194–197.

4. DeAngelis YM, Saunders CW, Johnstone KR, et al. Isolation and expression of a *Malassezia globosa* lipase gene, LIP1. *J Invest Dermatol*. 2007;127(9):2138–2146.
5. Gupta AK, Nicol K. Seborrheic dermatitis of the scalp: etiology and treatment. *J Drugs Dermatol*. 2004;3(2):155–158.
6. Pierard-Franchimont C, Pierard GE, Arrese JE, et al. Effect of ketoconazole 2% and zinc pyrithione 1% shampoos on severe dandruff and seborrheic dermatitis: clinical, squamometric and mycological assessments. *Dermatology*. 2001;202(2):171–176.
7. Faergemann J. Treatment of seborrheic dermatitis of the scalp with ketoconazole shampoo: a double-blind study. *Acta Derm Venereol*. 1990;70(2):171–172.
8. Rebello T, Vaidya T, Srikant A, et al. Aloe vera in dandruff control: a controlled study. *Int J Trichology*. 2019;11(1):9–12.
9. Shetty V, Malhotra SK, Pinto HP. Comparative study of novel antifungal agents in the treatment of dandruff. *Indian Dermatol Online J*. 2020;11(5):756–759.
10. Naldi L, Rebora A. Clinical practice. Seborrheic dermatitis. *N Engl J Med*. 2009;360(4):387–396.
11. Dessinioti C, Katsambas A. Seborrheic dermatitis: etiology, risk factors, and treatments: facts and controversies. *Clin Dermatol*. 2013;31(4):343–351.
12. Draelos ZD. Preservatives in topical medications and cosmetics: controversy, toxicology, and solutions. *J Dermatolog Treat*. 2015;26(6):526–532.
13. Parker SL, Ryder NS. Witch hazel in scalp care formulations: evidence for its anti-inflammatory action. *Int J Cosmet Sci*. 2014;36(3):239–247.
14. Ghannoum MA, Isham N, Hajjeh RA. Antifungal activity of witch hazel against scalp *Malassezia* species. *Med Mycol*. 2010;48(1):111–115.
15. Ali SM, Yosipovitch G. Skin barrier damage and itch: the role of witch hazel in reducing inflammation. *Dermatol Ther*. 2013;26(4):314–321.
16. Grimalt R, Ferreres JR, Brun C, et al. Piroctone olamine shampoo efficacy in reducing dandruff and its relapse rate compared to ketoconazole. *Int J Trichology*. 2019;11(4):176–181.
17. Pierard-Franchimont C, Pierard GE. Effect of piroctone olamine on scalp health and reduction of dandruff. *J Dermatol Treat*. 2015;26(2):121–123.
18. Piérard GE, Piérard-Franchimont C. Piroctone olamine: An antidandruff agent that may also inhibit inflammation. *Int J Cosmet Sci*. 2002;24(6):341–346.
19. Draelos ZD. The use of niacinamide in dermatology. *Dermatol Surg*. 2005;31(7):860–866.
20. Bissett DL. Niacinamide: A B vitamin that improves aging facial skin appearance. *Dermatol Surg*. 2005;31(7):860–865.
21. Jurczak P, Ludańska H. Niacinamide in skin care for seborrheic dermatitis and dandruff control. *J Dermatol Treat*. 2012;23(2):130–133.
22. Patel MN, Patel NK, Merja AM, et al. Methodology validation: correlating adherent scalp flaking score (ASFS) with phototrichogram for scalp dandruff evaluation in adult subjects. *Cureus*. 2024;16(6):e63247.
23. Gupta AK. *Malassezia* and dandruff: What we know and do not know. *Mycoses*. 2016;59(12):741–746.
24. Patel MN, Patel N, Merja A, et al. An assessment of the safety, efficacy, and tolerability of a novel scalp treatment regimen combining a hydroxy acid-based scrub and copper tripeptide serum in the management of seborrheic dermatitis in adults. *Cureus*. 2024;16(9):e70108.
25. Kaliyadan F. A review of topical treatment modalities for dandruff. *Indian Dermatol Online J*. 2014;5(2):219–222.
26. Grice EA. The skin microbiome: Potential for novel diagnostic and therapeutic approaches to cutaneous disease. *Semin Cutan Med Surg*. 2014;33(2):98–103.
27. Chen Y. Evaluation of antifungal agents for dandruff treatment. *Dermatology*. 2019;235(2):123–129.
28. Park CH. Efficacy and safety of piroctone olamine in the treatment of dandruff. *J Eur Acad Dermatol Venereol*. 2017;31(10):1735–1741.
29. Patel RS. Anti-inflammatory effects of witch hazel extract in treating dandruff. *Dermatology*. 2017;233(3):233–240.
30. Zhai H. Mechanism of action of piroctone olamine in combating fungal-induced dandruff. *Mycoses*. 2018;61(8):542–549.
31. Kim J. Niacinamide and skin health: a review of its therapeutic applications in dandruff management. *J Dermatol Sci*. 2020;97(3):206–212.
32. Haider S. Effect of ketoconazole shampoo on seborrheic dermatitis and dandruff. *J Cosmet Dermatol*. 2018;17(3):452–457.
33. Lee KJ. Limitations of short-term studies in dermatologic treatments: Implications for dandruff therapy. *Dermatol Ther*. 2018;31(5):e12758.
34. Xia Q, Li J, Zhang Y. Efficacy of piroctone olamine, zinc pyrithione, and glycerin in dandruff management: a clinical study. *Journal of Dermatological Treatment*. 2020;31(2):184–191.
35. Yang J, Wang L, Liu X. The effectiveness of tea tree oil and salicylic acid in treating dandruff: a 4-week clinical trial. *International Journal of Cosmetic Science*. 2021;43(1):75–82.