

# CLINICAL AND INSTRUMENTAL EFFICACY OF IVATHERM IVADERMASEB ANTI-DANDRUFF SERUM: A 28-DAY MONOCENTRIC IN-USE STUDY

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## Summary

Dandruff is a common scalp disorder characterized by excessive flaking and frequently associated with increased sebum production, discomfort, and impaired quality of life. Recent data suggest that the pathogenesis of dandruff is multifactorial; therefore, effective management requires a multimodal approach targeting the key mechanisms involved. Dermatocosmetic formulations that include active ingredients with antifungal and sebum-regulating roles represent an effective approach to improving scalp condition and reducing dandruff severity. This study evaluated the clinical efficacy and instrumental performance of Ivatherm – Ivadermaseb Anti-Dandruff Serum following 28 days of regular use. Twenty adult subjects with dandruff and oily scalp predisposition applied the serum every three days, on a clean scalp (after hair washing) for 28 consecutive days. Clinical dandruff severity was assessed by a dermatologist at baseline, Day 15, and Day 29 using a standardized clinical dandruff score. Scalp sebum levels were measured instrumentally with a Sebumeter® SM 815 at baseline and Day 29. After 15 days, the mean clinical dandruff score was reduced by 53.29%, reaching a 77.25% reduction after 28 days compared with baseline ( $p < 0.0001$ ). Instrumental measurements demonstrated a significant 23.91% decrease in scalp sebum levels after 28 days ( $p = 0.0004$ ). The product was well tolerated throughout the study, with no adverse reactions reported. These findings indicate that Ivatherm – Ivadermaseb Anti-Dandruff Serum is an effective and well-tolerated dermatocosmetic product for reducing dandruff severity and excess scalp sebum in subjects with dandruff and oily scalp predisposition.

**Keywords:** dandruff; scalp; sebum; sebaceous glands; cosmetics; dermatologic agents.

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## Introduction

Dandruff (*pityriasis capitis simplex*) is a desquamative disorder of the scalp, affecting nearly half of the adult population worldwide, with a similar prevalence across different ethnic or gender groups [1–3]. It is a chronic and recurrent condition, characterized by excessive scalp flaking and often accompanied by other symptoms such as pruritus, irritation and general scalp discomfort. Although often regarded as a minor cosmetic concern, dandruff can signifi-

cantly affect quality of life, representing both a physical and a psychological burden [4–6]. Due to its chronic nature and frequent relapses, many patients require repeated or continuous treatment in different forms, in order to maintain the control of the symptoms. It is also common for certain treatments, although initially effective, to lose their efficacy over time, requiring a new therapeutic regimen, while symptoms frequently recur once treatment is discontinued [2, 6].

Dandruff and seborrheic dermatitis (SD) are regarded as closely related conditions that share a

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common pathogenic mechanism. Current evidence suggests that dandruff represents the mildest manifestation within the spectrum of SD, as affected individuals generally do not show the clinical signs of inflammation characteristic of the latter [1,2,7,8]. Although both conditions share a scaly appearance of the scalp, dandruff is mainly characterized by diffuse white scales with absent or minimal visible inflammation, whereas SD typically presents with erythematous plaques. With regard to the affected area, dandruff is confined to the scalp, whereas SD may also involve other sebaceous-rich areas such as the face and ears [2,7,9,10,11].

The pathogenesis of dandruff is a complex, multifactorial process. Factors such as scalp dysbiosis, the presence and activity of *Malassezia* yeasts, sebaceous gland activity (most commonly overactivity) and epidermal barrier dysfunction might all play a role in the onset and persistence of dandruff. Another key aspect is the individual susceptibility of the patient, which largely determines how strongly these factors contribute to the disease [2,3,11,12]. All of them are strongly interconnected and interdependent, which explains the chronic and relapsing nature of the condition and the need for a multimodal treatment approach, as targeting each factor independently might not efficiently disrupt the underlying cycle [3,8,11,13,14].

While recent advances in research technology, such as genetic sequencing, have expanded our understanding of the scalp microbiome, the pivotal role played by the disruption of its physiological state in dandruff and seborrheic dermatitis has become increasingly evident. Among the factors involved, the influence of *Malassezia* species is central. *Malassezia* spp. are lipophilic yeasts that secrete extracellular lipases, which metabolize sebum triglycerides into free fatty acids, including oleic acid, that can penetrate the stratum corneum and trigger irritation in susceptible individuals [11,13,17]. However, these are commensal organisms, also found on healthy human skin, becoming pathogenic only under specific conditions. This indicates that fungal colonization alone is not sufficient to cause dandruff, with host susceptibility and scalp homeostasis acting

as important co-factors [11–13]. Significant changes in bacterial communities, particularly in *Cutibacterium* and *Staphylococcus* species, have also been associated with dandruff, contributing to an overall disruption of the microbial balance. A growing body of evidence supports the concept of scalp dysbiosis, in which an imbalance in the interactions between fungal and bacterial communities drives persistent low-grade inflammation, disrupts epidermal differentiation and weakens barrier integrity [15,16]. Consequently, the restoration of microbial balance is increasingly seen as an important goal of modern anti-dandruff cosmetic formulations.

Another key factor in the pathogenesis of dandruff is sebaceous gland activity. It is worth noting that the onset of dandruff is most often observed after puberty, which also represents a period of increased sebum production. The overactivity of the sebaceous glands provides a lipid-rich environment that is ideal for the proliferation and metabolism of *Malassezia* [1,11,17]. In this respect, as in the case of *Malassezia* colonization itself, dandruff occurrence is not directly correlated with sebum quantity, and many individuals with an oily scalp never develop dandruff. Instead, qualitative differences in sebum composition appear to play a more pronounced role in disease expression [11,12,17]. Nevertheless, when dandruff is already present, controlling scalp sebum may contribute to symptom improvement. For this reason, instrumental measurement of sebum production by photometric sebumetry represents a valuable objective parameter for assessing the efficacy of anti-dandruff products [1,11,17].

Impaired scalp barrier function is another factor that has been increasingly substantiated by recent studies on dandruff pathophysiology. Affected individuals often exhibit signs such as structural alteration of the stratum corneum, reduced levels of structural lipids, increased transepidermal water loss (TEWL) and accelerated corneocyte turnover, even in the absence of the clinically visible inflammation seen in seborrheic dermatitis [12,18,19]. Restoration of barrier integrity has been shown to correlate with clinical improvement, suggesting that effective dandruff management should also address the

normalization of epidermal homeostasis [3,18,19].

Available treatment regimens for dandruff generally combine therapeutic and dermatocosmetic approaches, aiming to reduce visible scaling and associated symptoms and to prevent relapse. Several topical agents are well recognized for their efficacy, including antifungal agents, keratolytics and topical corticosteroids. Dermatocosmetic products, in turn, incorporate active ingredients that modulate the scalp microbiome, improve barrier function and enhance the overall acceptability of treatment [20–25]. Topical pharmacological treatments are generally highly effective in reducing symptoms during acute exacerbations. However, relatively common adverse reactions and their limited cosmetic acceptability represent important limitations for prolonged use [7,21,24,25]. In this context, dermatocosmetic formulations are gaining increasing interest as options suitable for long-term maintenance as well as potentially effective alternatives in the active management of dandruff.

Considering the multifactorial pathogenesis of dandruff, effective dermatocosmetic management should simultaneously target microbial imbalance, excessive scalp desquamation and impairment of the scalp barrier. The investigated serum was therefore formulated using complementary ingredients with established cosmetic benefits for dandruff-prone scalp. Piroctone olamine is widely incorporated into dermatocosmetic anti-dandruff formulations because of its ability to reduce scalp colonization by *Malassezia* species while maintaining good cosmetic tolerability [20,21]. The formulation also contains *Ziziphus joazeiro* bark extract, a botanical ingredient used in scalp-care dermatocosmetic formulations. In addition, emollients (sweet almond oil) and humectants contribute to hydration of the scalp surface and support the maintenance of epidermal barrier function, complementing the overall dermatocosmetic strategy of restoring scalp homeostasis.

Therefore, the present study aimed to clinically and instrumentally evaluate the efficacy of Ivatherm – Ivadermaseb Anti-Dandruff Serum after 28 days of regular use under normal

conditions by assessing changes in clinical dandruff severity, scalp sebum levels and subjects' perception of product performance.

## Materials and Methods

### Study design and participants

This was a monocentric, open-label study evaluating the anti-dandruff efficacy, effect on scalp sebum and cosmetic acceptability of a leave-on serum (Ivadermaseb Anti-Dandruff Serum, ref. IV0042) under normal conditions of home use over 28 consecutive days (March–April 2024). The study was conducted in accordance with the Declaration of Helsinki and applicable Good Clinical Practice and cosmetic-product guidelines; all participants gave written informed consent before enrolment.

Twenty healthy adult subjects (18–70 years, both sexes, Fitzpatrick phototypes II–IV) with mild-to-moderate dandruff (clinical score 1–3) and a predisposition to oily hair were enrolled. Subjects with scalp or systemic conditions liable to interfere with the assessment, or receiving concomitant treatments affecting the scalp (e.g. psoriasis, atopic or contact dermatitis, tinea capitis, immunodeficiency, current antibiotic or antifungal use, pregnancy or breastfeeding), were not included. During the study, participants maintained their usual haircare routine and refrained from chemical hair treatments or introducing new cosmetic products.

### Product and application protocol

The investigational product was a leave-on scalp serum (Ivatherm - Ivadermaseb Anti-Dandruff Serum, ref. IV0042), presented as a clear, pale-yellow liquid. The formulation combined piroctone olamine and *Ziziphus joazeiro* bark extract as scalp-care ingredients, sweet almond oil as an emollient, and humectants (glycerin, butylene glycol, propanediol) intended to support scalp hydration. The subjects applied the serum to the scalp once every three days for 28 consecutive days, under normal conditions of home use. The serum was applied after washing and drying the hair, then gently massaged into the scalp.

### Efficacy assessment

Dandruff severity was scored by a dermatologist in three scalp regions (frontal, parietal and occipital) at baseline (T0), day 15 (D15) and day 29 (D29), using a six-point ordinal scale (0 = none to 5 = severe; Table 1). Scalp sebum was measured by grease-spot photometry (Sebumeter® SM 815, Courage + Khazaka, Germany) at the forehead, at baseline (T0) and after 28 days (D29), and expressed in  $\mu\text{g}/\text{cm}^2$ . Cosmetic qualities and perceived efficacy were assessed through a product-specific questionnaire completed by each subject at D29, using a four-point ordinal scale (0 = disagree to 3 = agree); results were expressed as the percentage of subjects assigning a score of 2 or 3. Throughout the study, subjects recorded any discomfort or adverse reaction in a daily log, and the dermatologist assessed the condition of the scalp at each visit. Standardized photographs were taken for five subjects at T0, D15 and D29.

### Statistical analysis

Data were compared between time points using a paired Student's t-test, with statistical significance set at  $p < 0.05$ .

## Results

The characteristics of the study population are summarized in Table 2.

### Clinical dandruff score

At baseline, the mean clinical dandruff score was  $2.78 \pm 1.08$ . It decreased to  $1.30 \pm 0.78$  at D15 and to  $0.63 \pm 0.55$  at D29, corresponding to reductions of 53.29% and 77.25% relative to baseline, respectively. Both reductions were statistically significant (paired Student's t-test,  $p < 0.0001$ ; Table 3).

The same trend was observed in all three scalp regions. In the frontal area, the mean score decreased from  $3.00 \pm 1.30$  to  $1.50 \pm 0.95$  at D15 (–50.00%) and to  $0.75 \pm 0.72$  at D29 (–75.00%). In the parietal area, it decreased from  $2.70 \pm 0.98$  to  $1.15 \pm 0.67$  at D15 (–57.41%) and to  $0.60 \pm 0.68$  at D29 (–77.78%). In the occipital area, it decreased from  $2.65 \pm 1.35$  to  $1.25 \pm 1.16$  at D15 (–52.83%)

and to  $0.55 \pm 0.69$  at D29 (–79.25%). All reductions were statistically significant ( $p < 0.0001$ ).

### Scalp sebum

The mean scalp sebum rate measured at the forehead decreased from  $154.75 \pm 49.17 \mu\text{g}/\text{cm}^2$  at baseline to  $117.75 \pm 40.55 \mu\text{g}/\text{cm}^2$  at D29, a mean reduction of  $37.00 \mu\text{g}/\text{cm}^2$  (–23.91%). This decrease was statistically significant (paired Student's t-test,  $p = 0.0004$ ; Table 4).

### Self-assessed cosmetic qualities and efficacy

At D29, all 20 subjects (100%) assigned a score of 2 or 3 to every questionnaire item. This applied to the cosmetic qualities assessed (easy application, easy and uniform spreading on the scalp, and no heavy feel on the hair) and to the perceived efficacy items (anti-dandruff effect, significant reduction of flakes and of dandruff, reduced scalp itching, reduced sebum secretion, hair remaining less greasy, soothing effect, fresh feel, no scalp dryness and improved scalp hydration). All subjects (100%) also agreed that they would buy and use the product and that they were satisfied with it after 28 days of use (Table 5).

Photographs taken at T0, D15 and D29 illustrated the visible reduction in scalp scaling over the course of the study, in agreement with the clinical scores (Figure 3).

## Discussions

The present study evaluated the anti-dandruff efficacy and the effect on scalp sebum of a leave-on serum under normal conditions of home use over 28 days. The product led to a marked and statistically significant reduction in clinical dandruff severity, with the mean score decreasing by 53.29% at D15 and by 77.25% at D29 relative to baseline. The improvement was consistent across all three scalp regions assessed, indicating a homogeneous effect over the whole scalp rather than a localized one. This is particularly relevant in dandruff, where scaling is typically diffuse and a uniform response across the scalp is therefore important.

The progressive reduction between D15 and D29 suggests a cumulative benefit with continued use, consistent with the chronic, multifactorial nature of dandruff, in which sustained action is generally required to control scaling and prevent relapse [3,8,11,13,14]. The presence of piroctone olamine and *Ziziphus joazeiro* bark extract in the formulation is in line with cosmetic strategies that address the microbial and desquamative components of dandruff [20,21], while sweet almond oil and humectants may contribute to maintaining scalp comfort and hydration during repeated use.

A significant reduction in scalp sebum was also observed, with a mean decrease of 23.91% after 28 days. Since excess sebum provides a lipid-rich environment favourable to the metabolism of scalp microflora [1,11,17], reducing surface sebum may create conditions less conducive to the processes involved in dandruff. This observation is consistent with the parallel improvement in clinical scaling, and further studies could help clarify the relationship between the two parameters.

The self-assessment results indicated a high level of perceived efficacy and cosmetic satisfaction, with all subjects responding favourably to every questionnaire item, including intent to repurchase and overall satisfaction. Importantly, no adverse reactions were reported by the subjects or observed by the dermatologist throughout the 28-day period. This favourable profile is particularly relevant in the context of dandruff management. As a chronic and relapsing condition, dandruff generally requires repeated or continuous use of care products to maintain control of the symptoms, and adverse effects of pharmacological treatments can be a limiting factor for prolonged use [7,21,24,25]. A dermatocosmetic serum that combines efficacy with pleasant cosmetic qualities, and with no adverse reactions reported during use, may therefore be a suitable option for regular, long-term scalp care, which in turn can support adherence to the treatment routine for patients with dandruff.

The main limitations of this study relate to the absence of a control group and to its relatively short duration, which does not allow the influence of possible seasonal variation in

dandruff severity to be ruled out. The 28-day period was nonetheless chosen deliberately, as it reflects the timeframe within which patients typically expect to observe visible results. The present findings should be confirmed in larger, controlled and ideally randomized studies.

## Conclusions

Dandruff is a common, chronic and recurrent scalp condition that generally requires repeated or continuous use of well-tolerated care products to keep the symptoms under control. In this context, the present in-use study evaluated the efficacy of the Ivatherm - Ivadermaseb Anti-Dandruff Serum over 28 days of regular home use.

The serum produced a significant reduction in clinical dandruff severity, reaching 77.25% after 28 days. This improvement was progressive over time and consistent across the frontal, parietal and occipital regions, indicating a homogeneous effect over the whole scalp. This clinical improvement was accompanied by a significant 23.91% decrease in scalp sebum, in line with the role of sebum in the development of dandruff. No adverse reactions were reported by the subjects or observed by the dermatologist, and the serum achieved a high level of efficacy and cosmetic satisfaction. These results indicate that the Ivatherm - Ivadermaseb Anti-Dandruff Serum is an effective option for the management of dandruff, providing a significant reduction in both dandruff severity and scalp sebum over 28 days, with benefits already apparent by Day 15. Combined with the absence of any adverse reaction reported during use, this makes it particularly suited to regular, long-term scalp care in individuals with dandruff or a dandruff-prone scalp.

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**Table 1. Clinical dandruff severity scoring scale**

| <b>Score</b> | <b>Severity</b> | <b>Description</b>                                                                    |
|--------------|-----------------|---------------------------------------------------------------------------------------|
| 0            | None            | —                                                                                     |
| 1            | Slight          | Barely perceptible scaling; small flakes resembling a coarse greyish powder           |
| 2            | Mild            | Minimal to intermediate scaling                                                       |
| 3            | Moderate        | Definite scaling; large, loosely attached flakes forming an irregular whitish surface |
| 4            | Pronounced      | Prominent scaling; flakes congealed into yellowish plates adhering to the scalp       |
| 5            | Severe          | Excessive, thick, yellowish and crusted adherent scaling                              |

*Six-point ordinal scale used by dermatologist to grade dandruff severity in each scalp region.*

**Table 2. Study population characteristics (n = 20)**

| <b>Characteristic</b>                        | <b>Value</b>                                  |
|----------------------------------------------|-----------------------------------------------|
| <b>Sex, n (%)</b>                            | <b>Female: 15 (75%); Male: 5 (25%)</b>        |
| <b>Age (years), mean <math>\pm</math> SD</b> | <b>44.8 <math>\pm</math> 12.1</b>             |
| <b>Age range (years)</b>                     | <b>21–64</b>                                  |
| <b>Fitzpatrick phototype, n (%)</b>          | <b>II: 2 (10%); III: 17 (85%); IV: 1 (5%)</b> |

*SD = standard deviation.*

**Table 3. Clinical dandruff score by scalp region and overall, at baseline (T0), day 15 (D15) and day 29 (D29)**

| Scalp region   | Baseline (T0)                     | D15                               | D29                               | $\Delta$ D15 vs T0 (%) | $\Delta$ D29 vs T0 (%) | p-value           |
|----------------|-----------------------------------|-----------------------------------|-----------------------------------|------------------------|------------------------|-------------------|
| Frontal        | 3.00 $\pm$ 1.30                   | 1.50 $\pm$ 0.95                   | 0.75 $\pm$ 0.72                   | -50.00%                | -75.00%                | <0.0001           |
| Parietal       | 2.70 $\pm$ 0.98                   | 1.15 $\pm$ 0.67                   | 0.60 $\pm$ 0.68                   | -57.41%                | -77.78%                | <0.0001           |
| Occipital      | 2.65 $\pm$ 1.35                   | 1.25 $\pm$ 1.16                   | 0.55 $\pm$ 0.69                   | -52.83%                | -79.25%                | <0.0001           |
| <b>Overall</b> | <b>2.78 <math>\pm</math> 1.08</b> | <b>1.30 <math>\pm</math> 0.78</b> | <b>0.63 <math>\pm</math> 0.55</b> | <b>-53.29%</b>         | <b>-77.25%</b>         | <b>&lt;0.0001</b> |

Values are expressed as mean  $\pm$  standard deviation ( $n = 20$ ).  $\Delta$  = percentage variation relative to baseline.  $p$ -values from paired Student's  $t$ -test; statistical significance set at  $p < 0.05$ .

**Table 4. Scalp sebum rate measured at the forehead, at baseline (T0) and day 29 (D29)**

| Parameter                                      | Baseline (T0)      | D29                | Change | Variation (%) | p-value |
|------------------------------------------------|--------------------|--------------------|--------|---------------|---------|
| Scalp sebum rate ( $\mu\text{g}/\text{cm}^2$ ) | 154.75 $\pm$ 49.17 | 117.75 $\pm$ 40.55 | -37.00 | -23.91%       | 0.0004  |

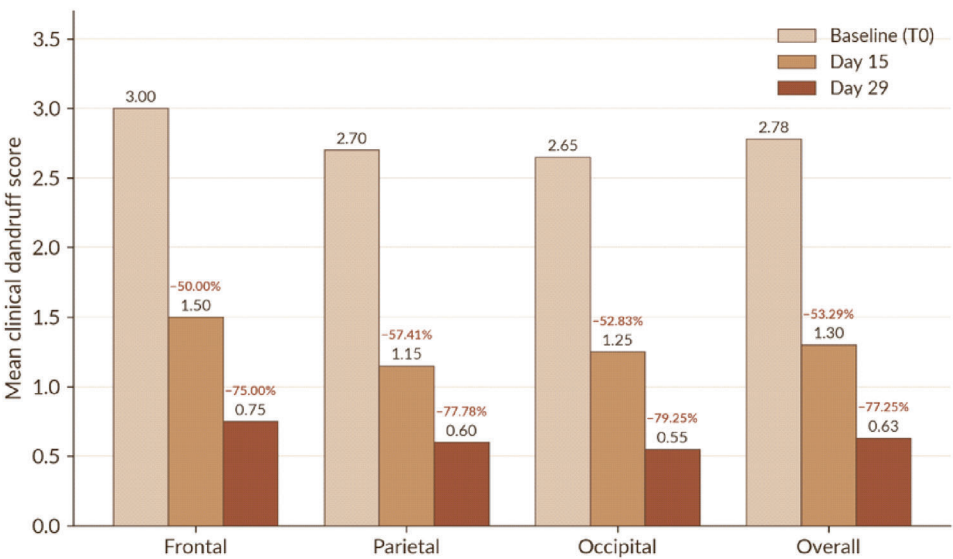
Values are expressed as mean  $\pm$  standard deviation ( $n = 20$ ), measured by grease-spot photometry (Sebumeter® SM 815).  $p$ -value from paired Student's  $t$ -test; statistical significance set at  $p < 0.05$ .

Table 5. Self-assessed cosmetic qualities and perceived efficacy after 28 days of use

| Questionnaire item                              | Subjects scoring 2 or 3 (n) | %    |
|-------------------------------------------------|-----------------------------|------|
| <b><i>Cosmetic qualities</i></b>                |                             |      |
| Easy application                                | 20                          | 100% |
| Pleasant fragrance                              | 20                          | 100% |
| Spreads easily and uniformly on the scalp       | 20                          | 100% |
| Does not leave the hair heavy after use         | 20                          | 100% |
| <b><i>Perceived efficacy</i></b>                |                             |      |
| Has an anti-dandruff effect                     | 20                          | 100% |
| Flakes significantly reduced                    | 20                          | 100% |
| Dandruff significantly reduced                  | 20                          | 100% |
| Scalp itching reduced                           | 20                          | 100% |
| Sebum secretion reduced                         | 20                          | 100% |
| Hair does not become greasy as quickly          | 20                          | 100% |
| Soothing effect on the scalp                    | 20                          | 100% |
| Scalp feels fresh and clean                     | 20                          | 100% |
| Does not dry the scalp                          | 20                          | 100% |
| Scalp feels more hydrated                       | 20                          | 100% |
| Cleansing effect on impurities                  | 20                          | 100% |
| <b><i>Overall appreciation</i></b>              |                             |      |
| Would buy and use the product                   | 20                          | 100% |
| Satisfied with the product after 28 days of use | 20                          | 100% |

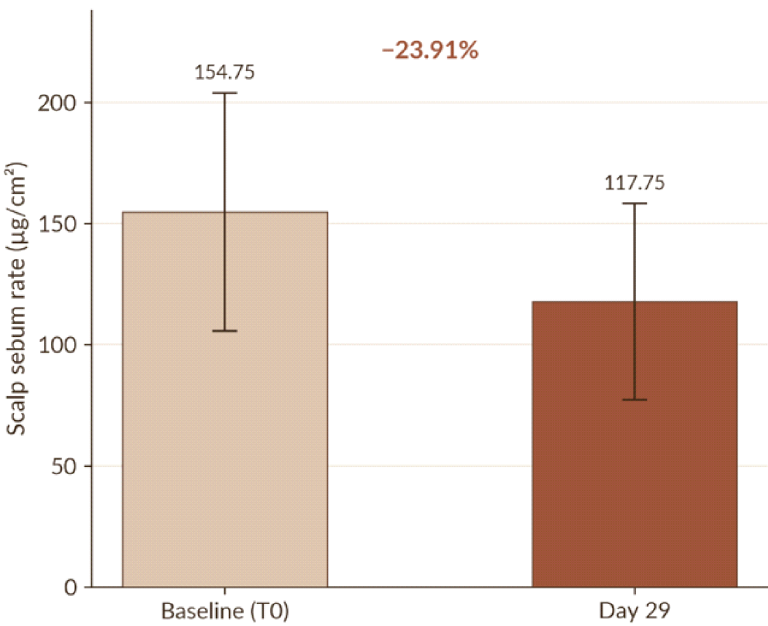
Responses given on a four-point ordinal scale (0 = disagree to 3 = agree). Results expressed as the number and percentage of subjects assigning a score of 2 or 3 (n = 20).

Figure 1. Mean clinical dandruff score by scalp region at baseline (T0), day 15 and day 29

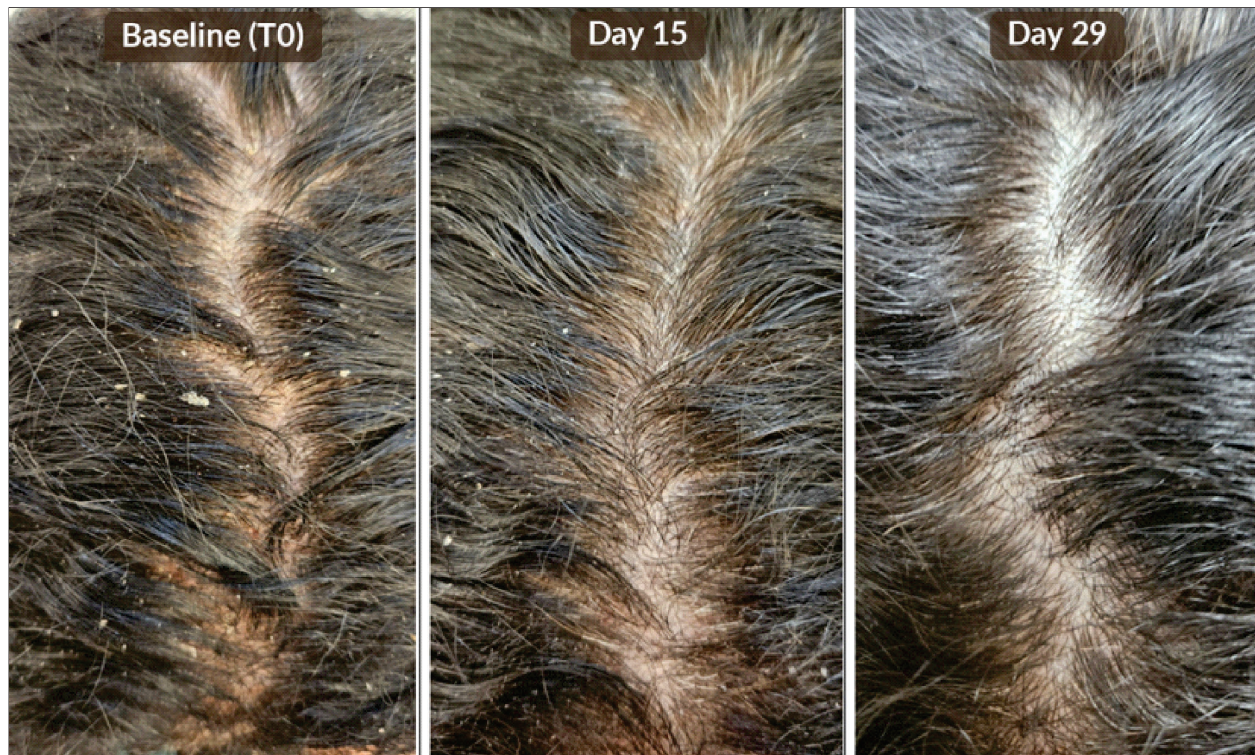


Mean clinical dandruff score ( $n = 20$ ) assessed by the dermatologist in the frontal, parietal and occipital regions, and overall, on a six-point ordinal scale (0 = none to 5 = severe). All reductions versus baseline were statistically significant (paired Student's  $t$ -test,  $p < 0.0001$ ). For clarity, standard deviations are reported in Table 3.

Figure 2. Scalp sebum rate at the forehead at baseline (T0) and day 29



Mean scalp sebum rate ( $n = 20$ ) measured by grease-spot photometry (Sebumeter® SM 815®). Error bars represent standard deviation. The 23.91% reduction versus baseline was statistically significant (paired Student's  $t$ -test,  $p = 0.0004$ ).



**Figure 3. Representative photographs of the scalp during the study.**  
*Representative clinical photographs of the same subject at baseline (T0), day 15 and day 29, showing the progressive reduction of visible scaling over the study period.*

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#### Conflict of interest

The authors declare that they have no affiliation with the company Ivatherm and are not in a situation of conflict of interest.

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