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Pilot study of topical management of folliculitis: clinical outcomes and safety in routine practice

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Contributions: Meda-Elena Stefancu, Dionisio Franco Barattini, Luca Barattini: conceptualization, formal and statistical analysis, writing – original draft; Meda-Elena Stefancu, Dionisio Franco Barattini: methodology; Meda-Elena Stefancu, Ionel Botnaru, Carmen Vizman: investigation; Ionel Botnaru, Dionisio Franco Barattini, Luca Barattini: writing – review & editing; Luca Barattini, Luca Stucchi: visualization; Luca Barattini: supervision; Dionisio Franco Barattini, Luca Stucchi: project administration. All authors have read and approved the final version of the manuscript and agreed to be accountable for any aspect of the work.

Conflict of interest: DFB is employed at Opera CRO, the contract research organization that managed the study; LB is a former intern at TIGERMED Italy, the company involved in data management and statistical analysis; LS is employed at BMG Pharma S.p.A., the sponsor of the study. MES, IB, and CV declare no conflict of interest. The funder had no role in the design of the study, in the collection, analyses, or interpretation of data, in the writing of the manuscript, or in the decision to publish the results.

Ethics approval and consent to participate: the Romanian Central Ethics Committee (National Commission for Bioethics of Medicines and Medical Devices - NCMMD) approved the study on October 6, 2022, with number not reported (site SC Salvosan Ciobanca S.r.l. in Zalău and site Darzas Aesthetic in Oradea, Romania) and May 11, 2023, with number not reported (site Nova-Clin Medical

Research Center in Timişoara, Romania). All participants were informed *a priori* about the purposes of the study, and they provided their informed written consent for study participation. All participants completed and signed a personal data treatment form in accordance with the General Data Protection Regulation (GDPR) 2016/679. As specified in the text of the manuscript, there was also an optional additional consent for the patients, allowing the use of their anonymized images for publication in a medical journal. No patients in the participating population agreed to the use of their anonymized images for publication, so this article does not include any individual images or videos. The trial was conducted in accordance with the Declaration of Helsinki and in adherence to the International Conference on Harmonisation, Good Clinical Practice, Medical Devices guidelines, ISO 14155, and Romanian regulatory requirements. Trial registration number: ClinicalTrials.gov as NCT05345093.

Availability of data and materials: The datasets used and analyzed during the current study are available upon reasonable request from the corresponding author.

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Abstract

Folliculitis is a common inflammatory skin condition for which non-antibiotic topical management options remain limited. This pilot study reports clinical performance, safety, and feasibility data from the use of a medical device gel containing hyaluronic acid (HA) and hydrogen peroxide used in dermatologic practice. Adults aged 18-45 years with a diagnosis of folliculitis applied the gel for 8 weeks according to the instructions for use. Clinical outcomes included lesion count, Total Severity Score (TSS), Investigator Global Assessment of Performance (IGAP), patient satisfaction, and Dermatology Life Quality Index (DLQI). Safety was assessed through adverse event (AE) reporting. Thirteen patients (mean age 30.1±7.7 years) were included. Enrollment rate and study conduct supported the feasibility of a future comparative trial. From baseline to week 8, mean lesion count showed a three-fold reduction, accompanied by a 66.6% improvement in TSS. Investigator- and patient-reported assessments indicated consistent clinical improvement with a positive impact on quality of life. Two mild and transient local effects were reported. Overall, these preliminary observations suggest favorable safety and performance of the gel in routine folliculitis management and support further controlled studies.

Introduction

Bacterial skin infections (BSIs) occur when microorganisms invade hair follicles or enter through small breaches in the skin, resulting in inflammatory lesions such as pustules, abscesses, erythema, and swelling. The severity and extent of these infections can vary, affecting the entire body surface or subcutaneous tissues. Minor BSIs encompass conditions such as folliculitis, furuncles, impetigo, and skin abscesses. On the other hand, more severe infections include cellulitis, wound infections, and substantial skin abscesses. The most prevalent causes of BSIs are *Staphylococcus* and *Streptococcus* strains. Among these, *Staphylococcus aureus* is particularly relevant because of its potential to induce bacteremia and serious complications such as endocarditis and osteomyelitis.[1]

Folliculitis is a serious bacterial, fungal, viral, or parasitic skin condition in which the hair follicle becomes infected or inflamed, forming a pustule or erythematous papule on the hair-covered skin that lies over the affected area. Its symptoms include mild pain, pruritus, or irritation, and its etiology is often unclear, but factors such as perspiration, trauma, friction, and occlusion of the skin have been identified as potential risk factors for infection. Bacterial folliculitis is typically caused by *S. aureus*, though cases of *Pseudomonas aeruginosa* (hot tub folliculitis) or other organisms have been documented on occasion. The majority of uncomplicated cases of folliculitis, characterized by a limited number of pustules, exhibit spontaneous resolution within several days. However, for more extensive manifestations, mupirocin and clindamycin have been proposed as topical antibiotic

options, and in treatment-resistant cases, oral cephalexin or dicloxacillin have proven to be an appropriate option. According to Zha *et al.*,[2] topical benzoyl peroxide is recommended as a first-line non-antibiotic option; however, in clinical practice it is sometimes replaced by hydrogen peroxide owing to its more favorable safety profile. Because of the limited penetration capacity and potentially harmful side effects of topical antibiotics, there is a growing focus on developing novel, safe, and effective dermatological preparations for routine use in clinical practice. In response to these needs, BMG Pharma S.p.A. (Milan, Italy) recently registered the medical device Ialuxid®, a formulation containing a patented combination. In the present pilot study, we tested this product, which we refer to as an investigational medical device containing Ialuvance® Complex (IMD-IC). Although this product has been widely used for different skin infections and disorders and its optimal performance and safety have been confirmed by the daily practice of thousands of dermatologists, there were few clinical trials to support these activities, limited only to the treatment of acne.[3,4] Our study aimed to partially address this clinical gap by testing the product in folliculitis treatment over an 8-week course; in addition, we adopted a pilot design to verify the feasibility of a future comparative study, and we followed the European legislation on medical devices. In fact, Regulation (EU) 2017/745 requires manufacturers to demonstrate the performance and safety of existing medical devices on the market; this must be done by performing specific trials indicated as post-marketing clinical follow-up (PMCF) studies involving populations affected by the same severity of disease and treated with the same duration and administration reported in the instructions for use of the product.

Materials and Methods

Research design and ethical considerations

This was a non-comparative, open-label, single-arm interventional pilot study involving an 8-week treatment with the IMD, which was administered to patients affected by folliculitis.

Originally, the idea was to conduct a comparative study to test IMD-IC in patients with folliculitis. In accordance with previous papers on folliculitis, we defined the main study design (double-blind randomized *vs.* placebo), the duration of treatment (2 months), and the primary outcome (number of lesions). Unfortunately, no data are available on the effect size of IMD-IC in folliculitis. Moreover, only limited evidence has been published for other therapies in this indication, and no sufficiently robust data were identified to support a sample size calculation *vs.* placebo.[5] For this reason, we reported a minimally important difference of 2±3.0 points in the number of lesions using a comparison of two means, with a significance level of 5% and a power of 80% to calculate that approximately 60 evaluable participants will be required for each group. The figures regarding the prevalence and incidence of this disease are few and contradictory: no other study on folliculitis was

ongoing in Romania at the time of starting our project. Therefore, it was not possible to reliably estimate in advance the patient enrollment rate for a clinical trial in folliculitis. In addition, the characteristics of the project recommended a multicenter design, although the potential investigators had never collaborated before. These considerations suggested first conducting a pilot study to evaluate IMD-IC in a limited number of subjects, and subsequently a randomized clinical trial (RCT) in a larger population, but only if the results of the pilot study proved favorable.

In particular, our goal was to achieve a monthly enrollment rate of at least 0.8 patients/month/site in this pilot study to ensure that the planned sample size for the future comparative study could be enrolled in a reasonable amount of time. This conservative approach should also allow us to collect preliminary data on the performance of the IMD-IC before calculating the final sample size for the comparative study.

The study protocol was approved by the Romanian Ethics Committee on October 6, 2022, without an assigned ID number, for the SC Salvosan Ciobanca S.r.l. site in Zalău and the Darzas Aesthetic site in Oradea. It was subsequently approved, likewise without an ID number, on May 11, 2023, for the Nova-Clin Medical Research Center site in Timișoara, as detailed in the ethical statement.

The trial was carried out in compliance with the Helsinki Declaration, ISO 14155, and Romanian legislation on clinical studies with medical devices.

The study enrolled outpatients who had standard daily dermatological visits at three Romanian private clinics selected for their experience treating folliculitis.

As required by the General Data Protection Regulation (GDPR) 2016/679, all participants completed a personal data treatment form and provided written informed consent for the study. In this form, it was specified that the images taken by the investigators at the different visits would only be used for a clinical trial. There was also an optional additional consent for the patients, allowing the use of their anonymized images for publication in a medical journal. No patient in the participating population agreed to sign this second consent.

The study was identified as NCT05345093 on ClinicalTrials.gov. BMG Pharma S.p.A. (Milan, Italy), the sponsor of the study, provided the medical devices needed for the studies to the clinics and had no role in the design of the study, and in the collection, analyses, or interpretation of data. The design and conduct of the study were aligned with the CONSORT 2010 recommendations, including the extension for pilot and feasibility trials.[6]

Tested product and concomitant treatment

The investigational product (IMD-IC) is a medical device already distributed in several European and non-EU countries. It contains the proprietary Ialuvance® Complex, a patented mixture of hyaluronic

acid (HA), hydrogen peroxide, and glycine. HA is a major extracellular matrix component and plays a central role in tissue homeostasis and repair.[7-9] Hydrogen peroxide, a mild antiseptic, contributes to wound healing by enhancing inflammatory signaling pathways and tissue regeneration.[10,11] Glycine, in turn, has been associated with improved epidermal barrier recovery.[12] Together, these components form a protective layer on the skin that helps preserve hydration and provides a physical barrier against microbial invasion. Based on these properties, IMD-IC has been considered suitable for several dermatological conditions, including folliculitis. In this trial, patients were instructed to self-apply the gel multiple times per day for 8 consecutive weeks, strictly following the instructions for use as mandated for PMCF studies.

During the course of the study, the administration of all drugs and therapies that were indicated as exclusion criteria was prohibited. On the contrary, the participants were permitted to continue receiving all previously prescribed therapeutic interventions for non-study-related clinical conditions.

Inclusion and exclusion criteria

Eligible participants were male or female adults between 18 and 45 years of age with a clinical diagnosis of folliculitis who consented to abstain from other dermatological treatments during the study. Exclusion criteria comprised any underlying dermatological or systemic condition that could interfere with the trial, known hypersensitivity to any of the gel's ingredients, or concomitant use of quaternary ammonium salts. Additional exclusions included recent therapies for folliculitis (topical or oral agents within the previous month), cosmetic or rejuvenation procedures within the last 6 months, facial aesthetic surgery or filler injections within the previous 3 months, and botulinum toxin injections to the face within 6 months prior to enrollment.

Outcome measures

In this pilot study, we evaluated the feasibility of the future comparative study according to the following parameters: monthly recruitment rate, duration of enrollment, choice of outcomes, and difficulties in their measurement. In addition, we also defined the criterion to determine whether to proceed with the future main RCT. We defined that at the end of the pilot study, a monthly enrollment rate of at least 0.5 patients/month/site should be achieved. In fact, this minimum result should ensure that the planned sample size of approximately 120 subjects could be enrolled in 2.5 years using 8 centers in the future comparative study.

The investigator collected preliminary data on performance by means of the following outcomes:

i) The number of lesions localized in the affected area. It should be the primary outcome in the main future double-blind randomized study.

ii) Total Severity Score (TSS). It was obtained by adding up the intensity of each specific clinical sign; the intensity was graded on a 4-point scale from "absent" to "severe".

iii) Treatment satisfaction questionnaire. Satisfaction was assessed in accordance with a 4-point scale with responses ranging from "very satisfied" to "not satisfied".

iv) Global Assessment of Performance (GAP). To assess this outcome, an investigator who was not involved in the patient visits blindly evaluated the photos taken by the investigator who visited the patient. The GAP was evaluated using a 4-point scale, ranging from 1 (very good) to 4 (poor performance).

v) Quality of life (QoL). It was evaluated using the Dermatology Life Quality Index (DLQI), which uses a total score ranging from 0 to 30. Scores of 0-1 indicate no effect; 2-5, a small effect; 6-10, a moderate effect; 11-20, a very large effect; and 21-30, an extremely large effect.

vi) Safety has been evaluated by collecting all adverse events (AEs) and serious adverse events (SAEs), comparing and evaluating them with the number of affected patients. The evaluation included related AEs, possibly related to or not evaluable. The incidence, type, and severity of AEs or SAEs were summarized in frequency tables using the Medical Dictionary for Regulatory Activities terms.

vii) Additional safety data were collected using the Investigator Global Assessment of Safety (IGAS) and the Patient Global Assessment of Safety (PGAS) assessments, which employed a 4-point scale, ranging from "very good safety" to "poor safety".

Sample size and statistical analysis

Due to the limited data available for folliculitis, the methodology proposed by Billingham *et al.* (2005) was applied.[13] According to this approach, enrolling 12 subjects was considered sufficient to demonstrate the clinical performance of IMD-IC. Taking into account a potential dropout rate of 10%, the final planned sample size was set at 13 patients.

Statistical analyses were performed using the statistical software (version 4.1.0; R Foundation for Statistical Computing). Continuous variables were summarized as means and standard deviations when normally distributed, or as medians and interquartile ranges otherwise. Categorical variables were presented as frequencies and percentages. For comparisons between baseline and follow-up, paired Student's *t*-tests or Wilcoxon signed-rank tests were employed depending on data distribution. The χ^2 test or Fisher's exact tests were used for categorical variables. The primary endpoint was specifically analyzed using paired *t*-tests or Wilcoxon tests, while repeated-measures approaches were used for secondary continuous outcomes. To further explore secondary endpoints, repeated-measures analysis of variance (ANOVA) or linear mixed-effects models were used, as appropriate.

The statistical methodology adopted in this pilot study mirrors that planned for the subsequent main study and was applied to evaluate the feasibility and appropriateness of the analytical strategy in this clinical context.

Results

Recruitment rate and duration of enrolment

The recruitment of the 13 participants began on November 11, 2022, and concluded on July 27, 2023. Therefore, the duration of enrollment was 8 months, and the enrollment rate was 1.6 patients/month in total (0.54 patient/month/center). This value complied with the total monthly recruitment rate planned for the main RCT (at least 0.5 patients/month/site), ensuring for the future RCT the enrollment of approximately 120 patients involving 8 centers for 2.5 years. The pilot study ended on September 22, 2023, the date of the last patient's visit.

Patients' characteristics

Four patients (30.8%) were males and 9 (69.2%) were females. Subjects were between 22 and 44 years old, with a mean age, height, weight, and body mass index (BMI) of 30.1±7.72 years, 170.30±7.47 cm, 74.50±18.60 kg, and 25.44±4.97, respectively, and all subjects belonged to the Caucasian ethnic group. No statistically significant difference resulted between sex for age, height, and weight (Table 1). No relevant findings were evidenced either in the medical history or during physical examination; no concomitant medication was recorded during the screening evaluation, and no major protocol deviations occurred concerning the study.

Choice of outcomes

The outcomes used in the pilot study were the same that investigators used in their routine visits, confirming that these outcomes are potentially available for future comparative studies.

Patients' dispositions and characteristics

Thirteen patients with folliculitis who met the inclusion criteria were enrolled in the trial and completed it.

All patients were included in the per-protocol, intention-to-treat, and safety populations, which coincided. The patient disposition is graphically displayed in Figure 1, and the demographic characteristics at baseline are shown in Table 1. Baseline characteristics were similar between sexes.

Total number of lesions

The number of lesions in the affected area at 8 weeks after the initiation of treatment was compared to day 0 (Table 2). The Wilcoxon test revealed a statistically significant threefold decrease in the number of lesions between the day 0 and day 56 visits (p=0.005). Figure 2 summarizes the total number of lesions at baseline (day 0) compared to day 28, indicating a significant decrease (p=0.034, Wilcoxon test).

Total Severity Score

Table 3 shows the TSS change between baseline, day 28, and day 56, demonstrating statistically significant reductions from baseline to day 28 (−33.3%, p=0.003) and day 56 (−66.6%, p=0.002).

Treatment satisfaction questionnaire

At the end of the treatment period (day 56), 10 patients (76.9%) declared to be very satisfied, and 3 (23.1%) were satisfied. No patient was moderately satisfied or not satisfied.

Global Assessment of Performance

At day 56, the GAP showed a mean score of 1.39±0.65. Specifically, very good performance was recorded in 9 patients, good performance in 3 patients, and moderate performance in 1 patient.

Dermatology Life Quality Index

At baseline, folliculitis had a moderate-to-very large impact on quality of life in the majority of patients. At day 56, a significant improvement in DLQI categories was observed, with 12 patients (92.3%) reporting either no effect or only a small effect of the disease on daily life, compared with 4 patients (30.8%) at baseline (p<0.001, Bhapkar test). Additional details are reported in *Supplementary Table 1.*

Safety

One patient reported two AEs during the study. Both AEs (application-site reactions, *i.e.*, pruritus) were resolved by the end of the study; they were judged mild and related to IMD-IC. No SAEs, adverse effects, or device deficiencies were reported during the study period. In addition, the patient and the investigator performed an overall safety evaluation at day 56. All judgments (100% of cases) for investigators and patients were positive (“very good” or “good”).

Discussion

This pilot study was designed to generate preliminary clinical and feasibility data on the use of IMD-IC gel in patients with folliculitis within the framework of a PMCF investigation. The predefined feasibility criterion was met, as the observed recruitment rate exceeded the minimum threshold established to support the conduct of a future randomized comparative study. This finding is particularly relevant given the limited epidemiological data available on folliculitis and the challenges associated with patient enrollment in prospective clinical trials for this condition.

From a clinical perspective, the exploratory performance outcomes indicated a consistent reduction in disease burden over the 8-week treatment period, as reflected by decreases in lesion count and TSS, alongside favorable investigator assessments and patient-reported outcomes. Improvements in quality of life, as measured by DLQI, further suggest a positive impact on patients' daily functioning. Although these findings should be interpreted with caution due to the open-label, non-comparative design and the small sample size, they provide an initial signal of clinical benefit that warrants further investigation.

The study was conducted in routine dermatological practice, using outcome measures commonly applied during standard clinical visits. This pragmatic approach supports the external validity of the observations and confirms the practicality of the selected endpoints for use in a larger, controlled trial. Safety outcomes were favorable, with only mild and transient local AEs reported, in line with the known tolerability profile of the device components.

Several limitations must be acknowledged. The pilot nature of the study, the absence of a control group, and the limited number of participants preclude definitive conclusions regarding comparative effectiveness. Moreover, the study was not powered to detect small treatment effects. Nevertheless, these limitations are intrinsic to feasibility studies and were considered acceptable within the context of PMCF and early evidence generation.

Overall, the results of this pilot study provide supportive preliminary data on performance, safety, and feasibility and inform the design and operational planning of a future randomized controlled trial in patients with folliculitis.

Conclusions

In this pilot PMCF study, IMD-IC gel demonstrated a favorable safety profile and consistent exploratory improvements in clinical and patient-reported outcomes in patients with folliculitis. While the limited sample size and non-comparative design do not allow definitive conclusions regarding efficacy, the findings provide useful feasibility and preliminary performance data. These results support the rationale for conducting a larger, randomized comparative study to further evaluate the clinical role of this topical medical device in the management of folliculitis.

References

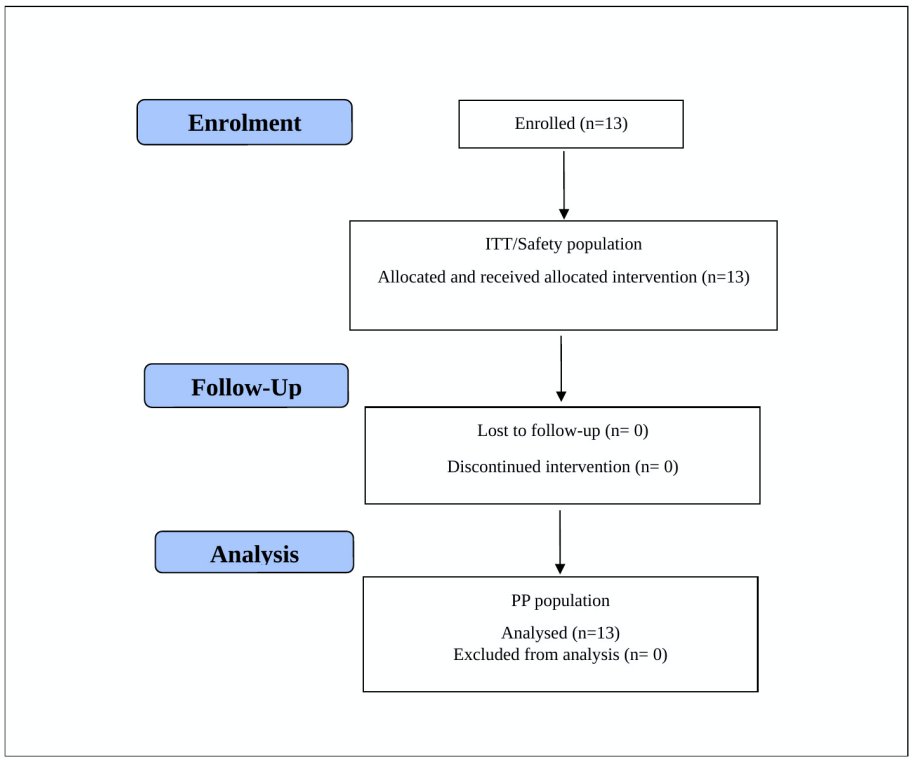
1. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. Clin Infect Dis 2014;59:e10-52.
2. Zha M, Usatine R. Common skin conditions in children and adolescents: bacterial infections. FP Essent 2024;541:14-9.
3. Veraldi S, Micali G, Berardesca E, et al. Results of a multicenter, randomized, controlled trial of a hydrogen peroxide–based kit versus a benzoyl peroxide–based kit in mild-to-moderate acne. J Clin Aesthet Dermatol 2016;9:50-4.
4. Stefancu ME, Barattini DF, Botnaru I, et al. Performance and safety of the medical device Ialuxid Gel in the treatment of mild-to-moderate acne vulgaris: an open-label, noncomparative multicenter clinical trial. J Cosmet Dermatol 2025;24:e70084.
5. Lin HS, Lin PT, Tsai YS, et al. Interventions for bacterial folliculitis and boils (furuncles and carbuncles). Cochrane Database Syst Rev 2021;2:CD013099.
6. Eldridge SM, Chan CL, Campbell MJ, et al; PAFS consensus group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ 2016;355:i5239.
7. Pereira H, Sousa DA, Cunha A, et al. Hyaluronic acid. Adv Exp Med Biol 2018;1059:137-53.
8. Salwowska NM, Bebenek KA, Żądło DA, Wcisło-Dziadecka DL. Physiochemical properties and application of hyaluronic acid: a systematic review. J Cosmet Dermatol 2016;15:520-6.
9. Keen MA. Hyaluronic acid in dermatology. Skinmed 2017;15:441-8.
10. Kapoor P, Kumar S. Hydrogen peroxide in dermatology. Indian J Dermatol Venereol Leprol 2023;89:310-2.
11. Milani M, Bigardi A, Zavattarelli M. Efficacy and safety of stabilized hydrogen peroxide cream (Crystacide) in mild-to-moderate acne vulgaris: a randomized, controlled trial versus benzoyl peroxide gel. Curr Med Res Opin 2003;19:135-8.
12. Inoue K, Takei K, Denda M. Functional glycine receptor in cultured human keratinocytes. Exp Dermatol 2015;24:307-9.
13. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials registered in the UK Clinical Research Network. BMC Med Res Methodol 2013;13:104.

Table 1. Demographic characteristics and vital signs measurements at baseline visit (per-protocol population).

Characteristics at baseline		**Overall**	**Female**	**Male**	**p-value**
Age (years)	N	13	9	4	0.429*
	Mean (SD)	30.1 (7.72)	28.9 (7.36)	32.8 (8.96)	
	Median	29	24	32	
	Range	[22-44]	[22-41]	[23-44]	
Weight (kg)	N	13	9	4	NR
	Mean (SD)	74.5 (18.6)	68.4 (16.0)	88.3 (18.2)	
	Median	75	73	81.5	
	Range	[50-115]	[50-95]	[75-115]	
Height (cm)	N	13	9	4	NR
	Mean (SD)	170.3 (7.47)	166.7 (4.53)	178.5 (6.24)	
	Median	170	167	179.5	
	Range	[158-185]	[158-173]	[170-185]	
BMI (kg/m^2)	N	13	9	4	0.334*
	Mean (SD)	25.44 (4.97)	24.51 (5.26)	27.54 (4.09)	
	Median	25.26	24.39	25.94	
	Range	[19.05-34.06]	[19.05-34.06]	[24.66-33.6]	
Systolic blood pressure (mmHg)	N	13	9	4	0.209*
	Mean (SD)	118.5 (14.5)	115.0 (14.1)	126.3 (13.8)	
	Median	115	110	127.5	
	Range	[90-140]	[90-140]	[110-140]	
Diastolic blood pressure (mmHg)	N	13	9	4	0.800*
	Mean (SD)	77.5 (8.53)	77.9 (10.01)	76.5 (4.73)	
	Median	80	80	78	
	Range	[60-90]	[60-90]	[70-80]	
Heart rate (bpm)	N	13	9	4	0.118**
	Mean (SD)	76.9 (10.51)	72.4 (4.88)	87.0 (13.52)	
	Median	72	70	90	
	Range	[68-100]	[68-80]	[68-100]	

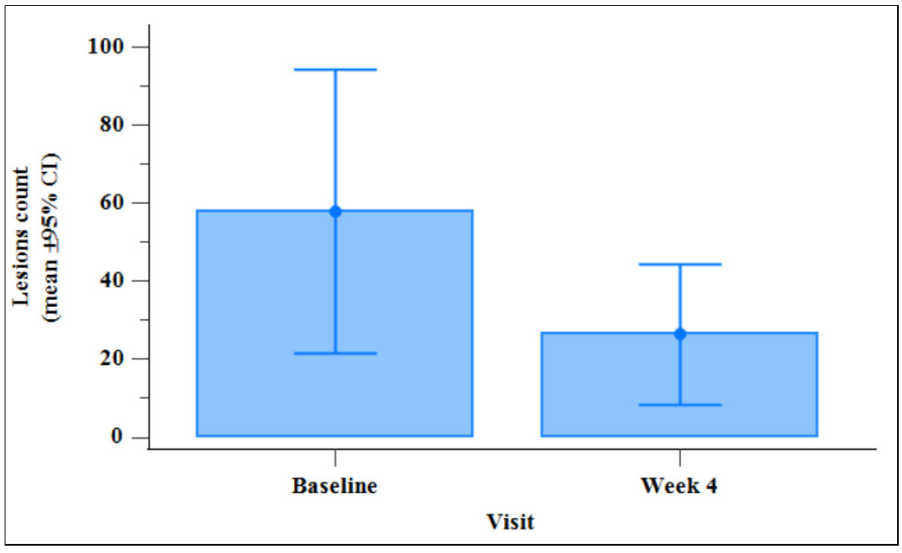
SD, standard deviation; BMI, body mass index; NR, not relevant; *analysis of variance; **Welch's *t*-test.

Figure 1. Flow chart of the study (CONSORT diagram).



ITT, intention-to-treat; PP, per-protocol.

Figure 2. Bar chart of the total number of lesions at day 28 compared to day 0.



CI, confidence interval.

Table 2. Decrease in the total number of lesions at day 56±4 compared to baseline.

	Day 0 visit	**Day 56±4 visit**	**p-value**
N	13	13	0.005*
Mean (SD)	57.8 (60.3)	17.7 (29.5)	
Median	20	5	
Range	[2-179]	[0-108]	

SD, standard deviation; *Wilcoxon test.

Table 3. Change in TSS from baseline to day 56 visit.

	Day 0 visit	**Day 28 ±2visit**	**Day 56±4 visit**	**p-value**
N	13	13	13	<0.001*
Mean (SD)	2.31 (0.95)	1.54 (1.69)	0.77 (0.60)	
Median	2	2	1	
Range	[1-5]	[0-3]	[0-2]	

SD, standard deviation; *Friedman test; day 0 *vs.* day 28: p=0.003; day 28 *vs.* day 56: p=0.008 (*post-hoc* Durbin-Conover pairwise Wilcoxon test).

Online supplementary material:

Supplementary Table 1. *Change in the DLQI total score at 8 weeks after the initiation of treatment compared to baseline.*