

# Efficacy and Safety of Clascoterone Cream 1% and Clindamycin 1.2%/Benzoyl Peroxide 5% Gel Treatment in Patients With Acne

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## ABSTRACT

**Background:** Clascoterone cream 1% is a topical androgen receptor inhibitor approved to treat acne vulgaris in patients  $\geq 12$  years of age. The American Academy of Dermatology recommends combining topical therapies that target different mechanisms of acne pathogenesis as first-line treatment for acne. This 16-week, open-label pilot study evaluated the efficacy and safety of clascoterone cream 1% combined with clindamycin 1.2%/benzoyl peroxide 5% gel in patients with acne.

**Methods:** Patients aged  $\geq 12$  years with moderate acne applied clascoterone cream 1% twice daily and clindamycin 1.2%/benzoyl peroxide 5% gel once daily for 12 weeks. Assessments included Investigator's Global Assessment (IGA) score; inflammatory, noninflammatory, and total lesion counts; Dermatology Life Quality Index (DLQI) score; tolerability (through local skin reactions); and safety (through adverse events) through week 16.

**Results:** Nine patients were enrolled in the study (female, 56%; White, 56%; mean [standard deviation (SD)] age, 33 [17] years). At week 16, all patients had an IGA score of clear (0) or almost clear (1); from baseline to week 16, there were significant decreases in lesion counts (mean [SD] percent reduction; inflammatory: 96.4 [6.0],  $P=0.007$ ; noninflammatory: 86.1 [15.3],  $P=0.009$ ; total: 92.0 [8.2],  $P=0.008$ ) and DLQI scores (mean [SD] reduction, 3.1 [2.1],  $P=0.014$ ). The treatment was well tolerated with no adverse events reported through week 16.

**Conclusions:** Based on data from 9 patients, combination treatment with clascoterone cream 1% and clindamycin 1.2%/benzoyl peroxide 5% gel is safe and effective to treat patients with acne.

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## INTRODUCTION

Acne vulgaris is an inflammatory skin disorder with a global prevalence of 9.4% and 231.2 million cases reported worldwide in 2019.<sup>1</sup> It is characterized by the presence of noninflammatory (closed or open comedones) and inflammatory (papules, pustules, nodules, and cysts) lesions.<sup>2</sup> Although acne is most common during adolescence, it can present at any age in people of both sexes.<sup>3</sup> Patients with acne have reduced quality of life and low self-esteem, especially those with more severe and extensive acne, adding to the high burden of disease.<sup>4</sup>

The pathogenesis of acne is driven by 4 main components: sebum production, follicular hyperkeratinization, bacterial colonization, and inflammation.<sup>2</sup> Sebum production is largely regulated by androgens; testosterone and dihydrotestosterone

bind to androgen receptors in sebocytes within the sebaceous gland, promoting the expression of genes that induce sebum production. This excess sebum leads to the accumulation of keratinocytes and colonization with *Cutibacterium acnes*, inducing inflammation and lesion formation.<sup>5-9</sup>

Clascoterone cream 1% is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years and older.<sup>10</sup> In two Phase 3 clinical trials (NCT02608450 and NCT02608476), clascoterone cream 1% monotherapy demonstrated superior efficacy vs vehicle for reducing acne severity and had a favorable safety and tolerability profile that was maintained for up to 9 months of treatment in an extension safety study.<sup>11-13</sup> While the mechanism of action of clascoterone cream 1% is unknown,<sup>10</sup> in vitro data suggest that it competes with dihydrotestosterone to bind androgen receptors and

inhibit downstream androgen-regulated sebum production.<sup>14,15</sup> In support of these *in vitro* data, 12 weeks of treatment with clascoterone cream 1% significantly reduced casual facial sebum levels in a clinical study of 40 patients with mild-to-moderate acne.<sup>16</sup>

Based on its efficacy and safety profile, clascoterone cream 1% is among the topical therapies (topical retinoids, benzoyl peroxide, topical antibiotics, salicylic acid, and azelaic acid) recommended by the American Academy of Dermatology (AAD) for the treatment of acne of any severity.<sup>17</sup> Notably, it is the only approved topical antiandrogen to treat acne.<sup>17</sup> The AAD recommends multimodal therapy with topical agents that target different aspects of acne pathogenesis as first-line treatment for acne vulgaris to optimize treatment efficacy.<sup>17</sup> As the only topical treatment that targets androgen-induced sebum production, clascoterone cream 1% is potentially a key component of combination treatment regimens.<sup>16</sup>

In a pilot study, clascoterone cream 1% was stable when combined with other topical acne medications, including clindamycin 1.2%/benzoyl peroxide 5% gel, *in vitro*.<sup>18</sup> However, as clascoterone cream 1% was evaluated as a monotherapy in clinical trials,<sup>11,12</sup> clinical data evaluating the efficacy and safety of clascoterone cream 1% combination therapy with other topical acne therapies are limited. The objective of this study was to investigate the efficacy and safety of clascoterone cream 1% in combination with clindamycin 1.2%/benzoyl peroxide 5% gel for the treatment of patients with moderate-to-severe acne.

## MATERIALS AND METHODS

### Study Design

This was a 16-week, open-label pilot study (ClinicalTrials.gov, NCT06336629) conducted at 2 clinics from December 19, 2023, to July 10, 2024. Institutional review board (Sterling IRB) approval was obtained for the study protocol. The study was conducted in accordance with Good Clinical Practice guidelines, the ethical principles described in the Declaration of Helsinki, and all local legal and regulatory requirements. All patients and/or parents or guardians provided written informed consent.

### Patients

This study enrolled male and nonpregnant female patients  $\geq 12$  years of age of any race with moderate or severe facial acne (Investigator's Global Assessment [IGA] score of 3 [moderate] or 4 [severe]). Patients were excluded from the study if they had an allergy, sensitivity, or hypersensitivity to any of the study medications; had a skin disease/disorder that could interfere with the evaluation of acne; or were using any of the following prohibited acne medications: over the counter acne medications or bleaching agents within 1 week of Visit 1; topical retinoids, topical antibiotics, benzoyl peroxide, dapson, cryotherapy, chemical peels, or microdermabrasion within 2 weeks of Visit 1;

oral antibiotics for acne or investigational drugs within 4 weeks of Visit 1; or oral retinoids or laser resurfacing and dermabrasion within 24 weeks of Visit 1.

### Treatments and Assessments

All patients applied a thin layer of clascoterone cream 1% to affected areas twice daily, once in the morning and once in the evening, and a thin layer of clindamycin 1.2%/benzoyl peroxide 5% gel to the face once daily in the evening for 12 weeks. Efficacy assessments included the IGA, inflammatory lesion count (ILC), and noninflammatory lesion count (NILC)—which were performed at screening (30 days before baseline), baseline (week 0), and every 4 weeks through week 16—and the Dermatology Life Quality Index (DLQI), administered at baseline and every 4 weeks through week 16. The IGA was used to assess acne severity on a 6-point scale from 0 (clear skin) to 5 (very severe). The DLQI was used to assess the impact of patients' acne on their quality of life, with scores ranging from 0 (no impact) to 30 (greatest impact).<sup>19</sup>

The primary efficacy endpoint was the percentage of patients achieving an IGA score of clear (0) or almost clear (1) at week 16. Secondary efficacy endpoints included the percent reduction in ILC, NILC, and total lesion count (TLC) from baseline to week 16. Improvement in skin-related quality of life was evaluated based on the reduction in DLQI score from baseline to week 16. Safety assessments included the frequency and severity of adverse events (AEs), assessed at week 4 and every 4 weeks through week 16, and the current severity of local skin reactions graded at screening, baseline, and every 4 weeks through week 16. The investigator graded the severity of erythema, dryness, peeling, and oiliness on a 5-point scale from 0 (absent) to 4 (severe) and interviewed patients to determine the severity of pruritus and burning/stinging, which was graded on a 6-point scale from 0 (absent) to 5 (severe).

### Statistical Analysis

As this is a pilot study, a formal justification for sample size was not included. The modified intention-to-treat population included all enrolled patients who completed the study and was used for all statistical analyses. Continuous variables were reported using means and standard deviations (SDs), and categorical variables using frequencies. Statistical significance was determined using 2-sided Wilcoxon rank sum tests (lesion counts) and Wilcoxon signed rank tests (DLQI). *P*-values  $< 0.05$  were considered statistically significant.

## RESULTS

### Demographics and Baseline Clinical Characteristics

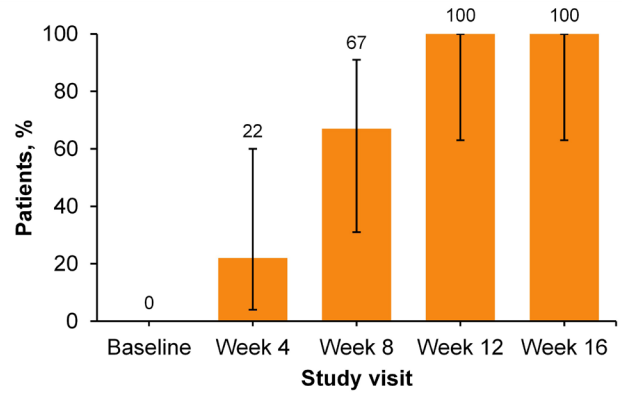
A total of 10 patients were screened: 1 was lost to follow-up, and the remaining 9 patients completed the study and were included in the analyses. Over half of the patients were female (55.6%) and White (55.6%), with a mean  $\pm$  SD age of  $33 \pm 17$

**TABLE 1.**

Demographics and Baseline Clinical Characteristics	
Demographics	Patients (N = 9)
<b>Age, years</b>	
Mean ± SD	33 ± 17
Range (min–max)	14–60
<b>Sex, n (%)</b>	
Female	5 (55.6)
Male	4 (44.4)
<b>Race, n (%)</b>	
Black	4 (44.4)
White	5 (55.6)
Clinical Characteristics	
IGA, n (%)	Patients (N = 9)
3 (moderate)	9 (100)
4 (severe)	0 (0)
<b>Lesion counts, mean ± SD</b>	
ILC	18.0 ± 5.0
NILC	13.0 ± 4.9
TLC	31.0 ± 5.8
DLQI, mean ± SD	5.7 ± 3.6

DLQI, Dermatology Life Quality Index; IGA, Investigator’s Global Assessment; ILC, inflammatory lesion count; max, maximum; min, minimum; NILC, noninflammatory lesion count; SD, standard deviation; TLC, total lesion count.

**FIGURE 1.** Proportion of patients with an IGA score of clear or almost clear through week 16.



Error bars show the 95% confidence intervals. IGA, Investigator’s Global Assessment.

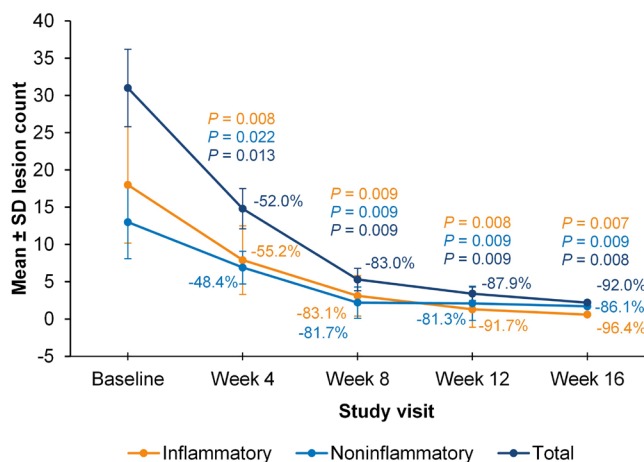
years (range, 14–60 years; Table 1). At baseline, 100% of patients had moderate acne (Table 1). Mean ± SD ILC was 18.0 ± 5.0, NILC was 13.0 ± 4.9, and TLC was 31.0 ± 5.8; mean ± SD DLQI score at baseline was 5.7 ± 3.6 (Table 1).

**Efficacy**

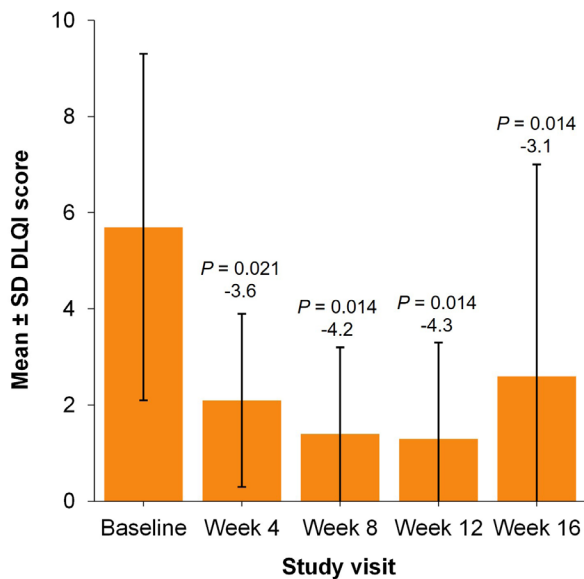
*IGA Score*

The percentage of patients with clear or almost-clear skin increased during the 16-week study following combination treatment with clascoterone cream 1% and clindamycin 1.2%/benzoyl peroxide 5% gel (Figure 1). At week 4, only 2 (22%) patients had an IGA score of clear (0) or almost clear (1; 95% confidence interval [CI], 4%–60%); 5 (56%) patients had mild acne and 2 (22%) had moderate acne (Figure 1). By week 8, the percentage of patients with an IGA score of clear or almost clear increased to 67% (95% CI, 31%–91%; Figure 1). At week 12, all 9

**FIGURE 2.** Reduction in lesion counts (inflammatory, noninflammatory, and total) through week 16.



Data labels show the mean percent reductions from baseline. P-values signify differences from baseline. SD, standard deviation.

**FIGURE 3.** Improvement in DLQI score through week 16.

The DLQI score ranges from 0 (no impact) to 30 (greatest impact); higher scores indicate greater impairment in quality of life.<sup>19</sup>

Data labels show the mean reductions from baseline. *P*-values signify differences from baseline.

DLQI, Dermatology Life Quality Index; SD, standard deviation.

(100%) patients achieved an IGA score of clear (3 [33%] patients) or almost clear (6 [67%] patients; 95% CI, 63%–100%), which was maintained at week 16 (clear, 4 [44%] patients; almost clear, 5 [56%] patients; 95% CI, 63%–100%; Figure 1).

#### Lesion Counts

Patients experienced significant reductions from baseline in lesion counts after 12 weeks of combination clascoterone cream 1% and clindamycin 1.2%/benzoyl peroxide 5% gel treatment (Figure 2). At week 4, the mean ILC, NILC, and TLC decreased by 55.2%, 48.4%, and 52.0%, respectively, compared with baseline, with continued reductions through week 16 (96.4%, 86.1%, and 92.0% vs baseline; Figure 2). The percent reductions in ILC, NILC, and TLC from baseline were statistically significant at all time points (all *P*<0.03; Figure 2).

#### Quality of Life

Significant reductions in DLQI scores were reported through week 16 in patients applying the combination treatment for 12 weeks. From baseline, the mean ± SD DLQI score decreased to 2.1 ± 1.8 at week 4 (3.6% ± 3.0% reduction from baseline; *P*=0.021), 1.4 ± 1.8 at week 8 (4.2% ± 2.7% reduction from baseline; *P*=0.014), 1.3 ± 2.0 at week 12 (4.3% ± 2.6% reduction from baseline; *P*=0.014), and 2.6 ± 4.4 at week 16 (3.1% ± 2.1% reduction from baseline; *P*=0.014; Figure 3).

**TABLE 2.**

#### Frequency and Severity of Local Skin Reactions Through Week 16

Measure	Baseline	Week 4	Week 8	Week 12	Week 16
<b>Erythema</b>					
Absent/trace	6 (67)	8 (89)	8 (89)	8 (89)	9 (100)
Mild	3 (33)	1 (11)	1 (11)	1 (11)	0 (0)
<b>Dryness</b>					
Absent/trace	9 (100)	9 (100)	9 (100)	9 (100)	9 (100)
Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>Peeling</b>					
Absent/trace	9 (100)	9 (100)	9 (100)	9 (100)	9 (100)
Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>Oiliness</b>					
Absent/trace	9 (100)	9 (100)	9 (100)	9 (100)	9 (100)
Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>Burning</b>					
Absent/trace	9 (100)	9 (100)	8 (89)	9 (100)	9 (100)
Mild	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
<b>Pruritus</b>					
Absent/trace	9 (100)	9 (100)	9 (100)	8 (89)	9 (100)
Mild	0 (0)	0 (0)	0 (0)	1 (11)	0 (0)

Data are shown as n (%).

**Safety and Tolerability**

Most local skin reactions were reported as absent or trace throughout the study. Three (33%) patients experienced mild erythema at baseline, and 1 (11%) experienced mild erythema through week 12; 1 (11%) patient reported mild burning at week 8 and 1 (11%) reported mild pruritus at week 12 (Table 2). All other instances of dryness, peeling, oiliness, burning, and pruritus were reported as absent or trace throughout the study, and all local skin reactions were absent or trace by week 16 (Table 2). No AEs were reported during the study.

**DISCUSSION**

The results of this 16-week pilot study support the efficacy and safety of combination treatment with clascoterone cream 1% and clindamycin 1.2%/benzoyl peroxide 5% gel. The primary and secondary efficacy endpoints were met. By the final study visit, all patients achieved clear or almost-clear skin, with significant reductions in lesion counts and corresponding improvements in quality of life. Combination treatment was well tolerated, with most tolerability parameters reported as absent or minimal, and no AEs reported through week 16. These findings in a small number of patients are promising and support the consideration of combination treatment with clascoterone cream 1% and clindamycin 1.2%/benzoyl peroxide 5% gel as an approach for the treatment of acne.

The efficacy of combination treatment as measured by the reduction in acne severity and lesion counts observed in the current study was comparable to that observed for patients treated with clascoterone cream 1% monotherapy and clindamycin 1.2%/benzoyl peroxide 5% gel monotherapy in clinical trials. In two Phase 3 clinical trials, clascoterone cream 1% monotherapy resulted in maximum reductions from baseline in the ILC, NILC, and TLC of up to 46.9%, 30.6%, and 37.3%, respectively, at week 12; corresponding reductions for patients treated with clindamycin 1.2%/benzoyl peroxide 5% gel monotherapy were 76.8%, 62.2%, and 69.1%, respectively.<sup>11,20</sup> Comparatively, patients treated with combination therapy in the current study experienced mean percent reductions at week 12 in the ILC, NILC, and TLC of 91.7%, 81.3%, and 87.9%, respectively, which were numerically greater than those observed for monotherapy, and 100% of patients achieved an IGA score of 0 or 1. These preliminary results suggest that combining clascoterone cream 1% and clindamycin 1.2%/benzoyl peroxide 5% gel may yield better treatment outcomes vs monotherapy for the treatment of acne.

The efficacy and safety of clascoterone cream 1% combined with other topical medications were evaluated in a small number of patients with acne, including a recent pilot study and 2 real-world case series. In an 8-week, open-label pilot study, the efficacy, safety, and tolerability of clascoterone cream 1% in combination with clindamycin phosphate 1.2%/adapalene

0.15%/benzoyl peroxide 3.1% gel were evaluated in patients with mild or moderate acne.<sup>21</sup> Patients experienced significant improvements in ILC from baseline to weeks 1 and 4, and the treatment was well tolerated.<sup>21</sup> In 2 recent case series, patients who added clascoterone cream 1% to their topical treatment regimens, including clindamycin 1%/benzoyl peroxide 5% gel and others, reported experiencing fewer AEs and, in some cases, greater satisfaction with their treatment.<sup>22,23</sup> Overall, patients experienced improvements in their acne following the addition of clascoterone cream 1% to their current topical therapies, demonstrating the benefit of including a topical antiandrogen in a variety of acne treatment regimens.<sup>22,23</sup>

One limitation of this pilot study is the small number of patients included, hindering the interpretation and generalizability of the results to the larger population with acne. Additionally, no control comparator groups (clascoterone cream 1% monotherapy, clindamycin 1.2%/benzoyl peroxide 5% gel monotherapy, or vehicle) were included, preventing direct comparisons of the efficacy and safety of combination treatment vs monotherapy. Nonetheless, this pilot study shows promising results for topical combination treatment targeting multiple pathogenic factors of acne (androgen-induced sebum, *Cutibacterium acnes*, and inflammation). Additionally, larger studies are needed to establish the efficacy and safety of concomitant use of these agents.

**CONCLUSION**

In this open-label pilot study, combination treatment with clascoterone cream 1% and clindamycin 1.2%/benzoyl peroxide 5% gel resulted in a reduction in acne severity from moderate at baseline to clear or almost clear at week 16, with significant reductions in lesion counts and improvement in quality of life. The treatment was well tolerated for 16 weeks, and no AEs were reported. These findings suggest that combining clascoterone cream 1% with clindamycin 1.2%/benzoyl peroxide 5% gel to address multiple aspects of acne pathogenesis, as recommended by the AAD, is a safe and effective treatment strategy for patients with moderate-to-severe acne.

**DISCLOSURES**

CK has nothing to disclose. LK has served as an investigator, speaker, advisory board member, or consultant for 3M, Abbott, Aclaris Therapeutics, Allergan, Amgen, Anacor Pharmaceuticals, Assos Pharmaceuticals, Astellas Pharma, Asubio Pharma, Bayer, Berlex Laboratories (Bayer), Biogen, BioLife, Biopelle, Blue Willow Biologics, Boehringer Ingelheim, Breckenridge Pharmaceutical, Celgene Corporation, Centocor, ColBar LifeScience, CollaGenex Pharmaceuticals, CombiMatrix Molecular Diagnostics, Connetics Corporation, Coria Laboratories, Dermik Laboratories, Dermira, Dow Pharmaceutical Sciences, DUSA Pharmaceuticals, Eli Lilly, Embil Pharmaceutical, EOS Pharmaceutical, Ferndale Pharma Group, Galderma, Genentech, GSK, Healthpoint,

Idera Pharmaceuticals, Innocutis Medical, Innovail, Johnson & Johnson, Laboratory Skin Care, LEO Pharma, L'Oréal, Maruho, Medical International Technologies, Medicis Pharmaceutical, Merck, Merz Pharma, Novartis, Noven Pharmaceuticals, Nucryst Pharmaceuticals, Obagi Medical Products, Ortho Neutrogena, PEDIAPharma, Pfizer, Pharmaderm, Promius Pharma, PuraCap Pharmaceutical, QLT, Quatrix, Quinova Pharmaceuticals, Sero (Merck-Serono International), SkinMedica, Stiefel Laboratories, Sun Pharma, Taro Pharmaceutical Industries, TolerRx, Triax Pharmaceuticals, UCB, Valeant Pharmaceuticals, Warner Chilcott, XenoPort, and ZAGE. NS and KK are employees of Sun Pharmaceutical Industries, Inc.

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