



# Effectiveness Test of *Epigallocatechin Gallate* Cream Formula in Acne Vulgaris Therapy

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**Keywords:** Epigallocatechin gallate, green tea, acne vulgaris, topical therapy, clinical efficacy, phytocosmetics.

**Abstract:** Acne vulgaris is a chronic inflammatory disease of the pilosebaceous follicles that affects more than 80% of adolescents and young adults. Conventional therapies such as antibiotics and topical retinoids have limitations in the form of resistance and irritation. Epigallocatechin gallate (EGCG) from green tea leaves (*Camellia sinensis* L.) has antibacterial, anti-inflammatory, and antioxidant activities that make it a safe natural anti-acne candidate. The preliminary pre-post clinical study without a control group aimed to evaluate the clinical efficacy and safety of a 6% topical EGCG cream in improving inflammatory and non-inflammatory acne lesions. Ten participants aged 17-50 years with active acne applied the cream twice daily in a total of six months. Lesion counts (papules, pustules, and comedones) were assessed monthly and analyzed using a paired t-test. Statistically significant reductions in inflammatory and non-inflammatory lesions were observed from the first month and sustained through month five ( $p < 0.05$ ). Mean papules decrease from  $9.40 \pm 5.97$  to  $3.0 \pm 3.13$ , pustules from  $1.70 \pm 1.57$  to 0, and comedones from  $21.5 \pm 10.76$  to  $4.20 \pm 3.05$ . Safety was evaluated through clinical monitoring and irritation testing, with no significant adverse reaction reported. Although limited by the small sample size and absence of a comparator group, these findings suggest that topical EGCG cream demonstrates preliminary efficacy and good tolerability.

## Introduction

Acne vulgaris is a chronic skin disease commonly experienced by adolescents and young adults, with a prevalence of over 80% in the 11-30 age group. The pathogenesis of acne involves increased sebum production, colonization by *Propionibacterium acnes* and *Staphylococcus epidermidis* bacteria, and an inflammatory response that leads to the formation of comedones and pustules (1, 2). Conventional therapies such as topical and oral antibiotics, retinoids, and benzoyl peroxide are often used, but they have limitations such as bacterial resistance, skin irritation, and systemic side effects, necessitating safer, natural-based alternative therapies (3-5).

Green tea (*Camellia sinensis* L.) is known to be rich in polyphenols, especially catechins, with epigallocatechin gallate (EGCG) as the main component ( $\pm 36\%$ ). EGCG has various pharmacological activities, including antioxidant, antibacterial, and skin-lightening effects. Several studies have shown that EGCG can inhibit the  $5\alpha$ -reductase type 1 enzyme, thereby reducing excessive sebum production and inhibiting the growth of *P. acnes* and *S. epidermidis* (1, 3, 4, 6, 7). The choice of EGCG was also based on previous

studies showing that EGCG can reduce skin depigmentation (8, 9), reduce inflammation (10), and reduce sebum (1). It can even kill antibiotic-resistant *Acinetobacter baumannii* bacteria (11). Therefore, EGCG in green tea leaves can be used as an alternative acne treatment.

Previous studies have developed cream preparations containing green tea leaf extract in various concentrations. A cream formula containing ethanolic green tea leaf extract at a concentration of 7% was shown to have good physical properties and antibacterial activity comparable to a commercial positive control preparation (Ristra® acne cream) (12). Furthermore, the optimum formulation of the ethyl acetate fraction of green tea leaf extract with an EGCG concentration of 6% produced an anti-acne cream that was stable both physically and chemically and was able to inhibit the growth of *S. epidermidis* for three months of storage (13). In the study of (13), the dosage used was a concentration of 6% in the optimization of the formula that had been tested for physical and chemical stability. Furthermore, efforts to increase EGCG stability have been investigated through the addition of natural antioxidants. The study results showed that vitamin C was

more effective than vitamin E or a combination of both in maintaining EGCG levels in the ethyl acetate fraction of green tea leaves during storage (13). However, clinical data evaluating the effectiveness of topical EGCG in acne patients remain limited, particularly in real-world and long-term applications.

The safety of using a 6% EGCG cream has also been tested in both animal models and in phase 1 clinical trials. Skin irritation tests on albino rabbits and in humans (20 respondents aged 17-45 years) showed that the EGCG cream did not cause irritation or allergic reactions after 21 days of use (14). Thus, previous research demonstrates that EGCG from green tea leaves has promising anti-acne activity, can be formulated stably into a cream, and is safe for topical use. Based on these findings, this study was conducted as an exploratory pilot clinical study to evaluate the clinical efficacy and safety of a topical cream containing 6% EGCG in reducing inflammatory and non-inflammatory acne lesions. The study aimed to generate preliminary clinical evidence regarding the potential of EGCG as a phytocosmetic active ingredient for acne management. The design was selected to assess feasibility, observe treatment trends over time, and provide initial data to inform the design of future randomized controlled trials.

## Methodology

### Research Design

The study was designed as a pilot exploratory clinical study with a pre-post study design to evaluate the preliminary clinical efficacy and safety of topical EGCG cream in patients with acne vulgaris on improving inflammatory (papules, pustules) and non-inflammatory (blackheads) acne lesions after six months of topical use. The study did not include a control group and therefore was intended primarily as a proof-of-concept investigation prior to larger controlled trials.

### Location and Time

The cream preparation was carried out at the Pharmacy Laboratory of Sultan Agung Islamic University (Unissula) Semarang, while the clinical trial was conducted on patients with active acne obtained through a collaboration with Siroto Pharmacy. The study was conducted from September 2021 to August 2022. Ethical approval was obtained from the Universitas Islam Sultan Agung under approval number no.6/1/2026/Komisi Bioetik. All participants provided written informed consent prior to enrolment in the study.

### Participants and Sample Size

Ten respondents were selected using a purposive sampling method. Inclusion criteria were age 17-50 years, active acne with a minimum of 20 blackheads and 10 papules, no other skin conditions (e. g., dermatitis, psoriasis, or skin infections), no history of allergies to cosmetics, and willingness to participate and sign an informed consent. Exclusion criteria were age < 17 years or > 50 years, have active skin disease other than acne, and history of cosmetic allergies or hypersensitivity to formula components. A formal sample size calculation and statistical power analysis were not performed, as the

primary objective was to explore treatment feasibility and obtain initial clinical observations prior to conducting larger controlled studies.

### Intervention and Compliance Monitoring

Participants were instructed to apply 6% EGCG cream twice daily (morning and evening) to clean and dry facial skin for a total duration of six months. Participants were advised not to use other anti-acne medications or cosmetic treatments during the study period. Treatment adherence was monitored through monthly follow-up visits, during which participants were asked about their application routine and remaining cream volume was checked. Participants also received reminders to ensure consistent application throughout the study period. To minimize potential confounding variables, participants were instructed to maintain consistent daily skincare routines throughout the study period and to avoid the use of other topical or systemic anti-acne treatments. Information regarding skincare practices, concurrent medication use, and relevant medical history was obtained at baseline through structured interviews. However, as this study was designed as an exploratory clinical investigation, certain factors such as dietary habits, hormonal fluctuations, and environmental influences were not strictly controlled. These variables may have influenced treatment outcomes and are acknowledged as limitations of the study.

### Outcome Assessment

The primary outcome was the change in the number of acne lesions, including inflammatory lesions (papules and pustules) and non-inflammatory (comedones). Lesion counts were performed monthly. All assessments were conducted by the same trained evaluator to minimize inter-observer variability. However, due to the exploratory design of the study, assessor blinding was not implemented, which may introduce potential observer bias.

### Test Cream Formula

The EGCG cream formula used is an oil-in-water (O/W) preparation with the following composition (per 100 g): Epigallocatechin gallate: 6.00 g, Propylene glycol: 2.10 g, Span 80: 2.20 g, Tween 80: 5.70 g, Sorbitol: 20.0 g, Stearic acid: 5.00 g, Virgin Coconut Oil (VCO): 20.0 g, Citric acid: 0.70 g, Ascorbic acid: 0.06 g, Triethanolamine: 2.45 g, Methylparaben: 0.25 g, Propylparaben: 0.15 g, and Aqua distillate ad 100 g. The cream used has previously undergone physical and chemical stability tests, preclinical antibacterial tests, and phase I clinical trials (primary and secondary irritation tests), all of which have been found to be safe for use (4, 7, 12, 13).

### Anti-Acne Test

Eligible participants who successfully fulfilled all predefined inclusion criteria were required to adhere to a treatment regimen involving the topical application of EGCG cream twice daily specifically during the morning and evening hours targeting facial areas characterized by active acne lesions. The clinical evaluation phase spanned a total duration of six months, commencing from the initial baseline assessment (Month 0) and extending through to Month 6, with data collection facilitated by mandatory monthly follow-up visits. Throughout each

**Table 1.** Severity classification of acne vulgaris based on lesion counts.

Level	Blackheads	Papules/Pustules
Mild	< 10	< 10
Moderate	< 20	> 10-50
Severe	> 20-50	> 50-100
Very Severe	> 50	> 100

scheduled appointment, a rigorous quantification of acne lesions was performed and systematically recorded to ensure a comprehensive longitudinal tracking of the treatment's clinical progression (**Table 1**).

### Safety Test

An irritation test was conducted to assess the safety of topical application of 6% EGCG cream on human skin before and during long-term use. This study used 10 participants, the same as the efficacy test subjects, aged 17-50 years, with no history of skin allergies. All participants signed informed consent specifically for the irritation test (15, 16). Approximately 0.5 g of 6% EGCG cream was applied to the volar area of the inner forearm, covering an area of approximately 4 cm<sup>2</sup>, then covered with a semi-occlusive patch for 24 hours. As a comparison, a base cream (placebo) without EGCG was applied to the contralateral arm. After the patch was removed, the test area was observed at 1, 24, and 48 hours for signs of erythema (redness) and edema (swelling).

### Data Analysis

Data were analyzed using a paired t-test to compare the number of lesions at baseline (month 0) with each month

of observation (months 1 to 6). A p-value < 0.05 was considered statistically significant. Data are presented as mean ± standard deviation. Normality of data distribution was assessed prior to analysis. Given the small sample size, the findings are considered preliminary and hypothesis-generating rather than confirmatory.

## Results and Discussion

This study aimed to evaluate the effectiveness of topical epigallocatechin gallate (EGCG) cream in reducing the number of acne lesions in subjects with acne vulgaris. The acne lesions assessed included papules, pustules, and comedones, representing two major types of acne: inflammatory and non-inflammatory. Results obtained over 5 months of observation showed a consistent pattern of improvement, with a significant reduction in all lesion types compared to baseline (month 0).

Quantitatively, **Table 2** shows that the mean number of papules decreased from 9.4 ± 5.97 at month 0 to 3.0 ± 3.13 at month 5. The number of pustules, which was initially 1.7 ± 1.57, decreased drastically from the first month, reaching 0 at month 3 and remaining stable without recurrence until the end of the observation period. Meanwhile, the number of blackheads decreased from 21.5 ± 10.76 at month 0 to 4.2 ± 3.05 at month 5. Due to the small sample size, normality assumptions were assessed using descriptive distribution patterns. However, results should be interpreted cautiously as normality testing in small samples has limited reliability. Statistical analysis using a paired t-test showed that all these decreases were significant (p < 0.05) even from the first month of use (**Table 3**). Thus, EGCG cream demonstrates both early onset and sustained efficacy against acne. The present study demonstrated a reduction in both inflammatory and non-inflammatory acne lesions over the

**Table 2.** Average number of acne lesions after EGCG cream application.

Month	Mean SD		
	Papule	Pustule	Blackheads
0	9.40 ± 5.97	1.70 ± .57	21.50 ± .76
1	7.80 ± 5.35	1.00 ± .41	15.30 ± .67
2	6.80 ± .59	0.40 ± .97	10.20 ± .67
3	5.50 ± .01	0.00 ± .00	7.90 ± .76
4	4.1 ± .57	0.00 ± .00	6.00 ± .19
5	3.0 ± .13	0.0 ± .00	4.20 ± .05

**Note:** Data are presented as the mean ± standard deviation (SD) of 10 respondents. There was a decreasing trend in the number of papules, pustules, and blackheads from month 0 to month 5.

**Table 3.** Statistical significance (p-values) of acne lesion reduction from baseline following EGCG cream application.

Lesion	p-value				
	Month-1	Month-2	Month-3	Month-4	Month-5
Papule	0.0031	0.0063	0.0035	0.0030	0.0018
Pustule	0.0013	0.0019	0.0075	0.0074	0.0075
Blackheads	0.0001	0.0019	0.0009	0.0004	0.0003

**Note:** Paired t-test between baseline (month 0) and observation month. A p-value < 0.05 is considered significant.

observation period. However, given the pre-post design without a control group, these findings reflect temporal changes rather than confirmed treatment effects. Although statistically significant differences were observed, the absence of a comparator group and the small sample size limit the ability to attribute these change solely to the intervention. Additionally, repeated comparison across multiple time points may increase the risk of type I error. Therefore, the observed improvements should be interpreted as preliminary observational findings that suggest potential benefit rather than definitive evidence of clinical efficacy.

These results align with previous literature confirming the benefits of EGCG as an anti-acne agent. A randomized, split-face clinical trial conducted by (17), used topical EGCG cream at concentrations of 1% and 5% in patients with acne vulgaris, showing a significant reduction in the Leeds score, which measures the number of inflammatory and non-inflammatory lesions. The effect was seen as early as week 4 and continued to improve until the end of the study at week 8, without any significant side effects. This study supports our findings that EGCG can provide clear clinical improvement within just a few weeks of use. Acne vulgaris is a chronic inflammatory disease of the pilosebaceous follicles with four main factors: hyperseborrhoea due to androgen hormone stimulation and 5 $\alpha$ -reductase enzyme activity; follicular hyperkeratinization leading to obstruction and comedone formation; colonization by *Cutibacterium acnes*; and inflammation mediated by proinflammatory cytokines and oxidative pathways. EGCG modulates almost all of these factors. First, EGCG is known to inhibit the 5 $\alpha$ -reductase enzyme, thereby reducing the production of dihydrotestosterone (DHT) which triggers excessive sebum secretion (18). The reduction in sebum reduces the substrate needed for *C. acnes* to grow, while reducing comedone formation. Second, EGCG has a strong anti-inflammatory effect. A study by (19) showed that EGCG can reduce the expression of pro-inflammatory cytokines such as TNF- $\alpha$ , IL-1 $\beta$ , and IL-6, as well as inhibit the activation of the NF- $\kappa$ B and AP-1 transcription pathways. These effects contribute to the reduction of papules and pustules, which are inflammatory lesions. Third, EGCG has antimicrobial properties against *C. acnes*. This mechanism

involves disrupting bacterial membrane integrity and inhibiting the production of inflammatory mediators by *C. acnes*. Thus, EGCG reduces bacterial colonization while reducing secondary bacterial-induced inflammation. Fourth, EGCG functions as a potent antioxidant. Acne is known to involve oxidative stress, including increased reactive oxygen species (ROS), which damage pilosebaceous follicles and exacerbate inflammation. EGCG increases the activity of endogenous antioxidants such as superoxide dismutase (SOD) and glutathione (GSH), thereby helping to balance the skin's redox status (18). Through this multi-target mechanism, EGCG is able to affect both non-inflammatory lesions (blackheads) and inflammatory lesions (papules and pustules). This explains why in our study, reductions were seen in all lesion types and were consistent from the first to the fifth month.

Safety is a crucial aspect of long-term acne therapy. Standard therapies such as benzoyl peroxide and topical retinoids are often associated with skin irritation, redness, and dryness. In contrast, topical EGCG in this study did not cause significant side effects. This is consistent with the report by (17) which found no major side effects, and the study by (19) which reported only mild erythema in a small proportion of subjects. This safety profile adds to EGCG's potential as an acne therapy, particularly in patients with sensitive skin or those who cannot tolerate conventional therapies.

Irritation test results showed that the 6% EGCG cream was non-irritating to human skin, both upon single exposure and repeated use over three weeks (Table 4). A mean value is 0.00, indicated no irritation, categorizing it as non-irritant according to the (15, 20). The absence of edema or inflammatory reactions indicates that the base components of the preparation (VCO, Tween 80, Span 80, sorbitol) are biocompatible with skin. EGCG itself has been reported to have a protective effect against oxidative stress and skin inflammation, suppressing the release of pro-inflammatory cytokines such as TNF- $\alpha$  and IL-1 $\beta$ , which contribute to the irritation response (19, 20). Furthermore, the presence of ascorbic acid in the formula acts as an additional antioxidant, helping stabilize the EGCG while reducing the potential for oxidation that can cause irritation (13). Studies by (17) also previously reported that topical application of EGCG at a

**Table 4.** Primary irritation test results of 6% EGCG cream.

Respondents	Mean SD			Category
	Erythema	Edema	Total Score	
1	0.00	0.00	0.00	Non-irritating
2	0.00	0.00	0.00	Non-irritating
3	0.00	0.00	0.00	Non-irritating
4	0.00	0.00	0.00	Non-irritating
5	0.00	0.00	0.00	Non-irritating
6	0.00	0.00	0.00	Non-irritating
7	0.00	0.00	0.00	Non-irritating
8	0.00	0.00	0.00	Non-irritating
9	0.00	0.00	0.00	Non-irritating
10	0.00	0.00	0.00	Non-irritating

concentration of up to 5% did not cause significant irritation in patients with acne vulgaris. These results strengthen clinical evidence that a 6% concentration of EGCG is safe for long-term use, thus potentially further developing it as a safe and effective anti-acne phytocosmetic active ingredient.

These research findings have broad clinical implications. First, the rapid onset of improvement from the first month suggests that EGCG may be a promising therapy for patients seeking rapid results. Second, the sustained significant reduction through the fifth month indicates a stable, long-term effect, suggesting that EGCG has the potential to be used as a maintenance therapy. Third, with its favorable safety profile, EGCG can be positioned as an alternative or complementary therapy to current standards. Furthermore, EGCG's ability to target multiple pathways in acne pathogenesis makes it unique compared to agents that only act through a single mechanism, such as antibiotics (antimicrobials) or retinoids (normalizing keratinization). This multi-target approach not only increases effectiveness, but may also reduce the risk of bacterial resistance.

Although the results of this study are promising, there are several limitations that should be noted. First, the sample size was relatively small (10 respondents), the generalizability of the results is still limited. Second, this study did not use a control group or comparison group with standard therapy, so its effectiveness relative to other therapies cannot be determined. Third, the evaluation was limited to clinical parameters such as lesion count, without measurement of laboratory biomarkers such as sebum levels, cytokine profiles, or *C. acnes* colonization. Therefore, further research with a randomized controlled clinical trial design on a larger sample size and longer duration is needed. The combination of EGCG with standard therapies such as retinoids or benzoyl peroxide is also interesting to explore, given its potential synergistic effects.

## Conclusion

Topical application of 6% EGCG cream demonstrated a reduction in both inflammatory and non-inflammatory acne lesions over the treatment period, suggesting its potential as a phytocosmetic agent for acne management. However, given the exploratory pre-post design, small sample size, absence of a control group, and lack of blinded assessment, these findings should be interpreted as preliminary evidence rather than definitive proof of clinical efficacy. Therefore, while EGCG shows promise due to its multi-target biological activities and favorable tolerability profile, further well-designed randomized controlled trials with larger sample sizes and standardized outcome measures are required to confirm its clinical effectiveness and establish its role in routine acne therapy.

## Abbreviations

EGCG = *Epigallocatechin gallate*

## Declaration

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## Conflict of Interest

The authors declare no conflicting interest.

## Data Availability

The datasets generated during this study are not publicly available due to commercial restrictions but may be available from the corresponding author on reasonable request.

## Ethics Statement

This clinical trial was approved by the Institutional Review Board of Universitas Islam Sultan Agung (Approval No. 6/1/2026/Komisi Bioetik). Written informed consent was obtained from all participants.

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