International Journal of Basic & Clinical Pharmacology
Shah HJ et al. Int J Basic Clin Pharmacol. 2025 Nov;14(6):983-988
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20253373

Original Research Article

Efficacy and safety of lactoferrin based cream (Siracilt™ acne) in the treatment of patients with mild to moderate acne vulgaris – a randomized, comparative and pilot study

Harsh J. Shah*, Jacky K. Pariyani, Kalyani V. Shinde

Department of Medical Affairs, Frimline Private Limited (a subsidiary of La Renon Healthcare Pvt. Ltd.), Ahmedabad, Gujarat, India

Received: 06 August 2025
Revised: 16 September 2025
Accepted: 24 September 2025

***Correspondence:**
Dr. Harsh J. Shah,
Email: harsh.shah@larenon.com

ABSTRACT

Background: This pilot study was planned to evaluate the efficacy and safety of Siracilt™ Acne (lactoferrin, azelaic acid, and niacinamide) cream and compare it with azelaic acid cream and clindamycin gel in the treatment of patients with mild to moderate acne vulgaris.
Methods: This study was a randomized, open-label active controlled, parallel group clinical trial. A total of 80 patients with mild to moderate acne vulgaris [investigator global assessment (IGA) score, 2 or 3] were randomized to receive Siracilt™ Acne cream, azelaic acid 10% cream, azelaic acid 20% cream, and clindamycin 1% gel for 4 weeks. The primary endpoint was the proportion of patients who achieved treatment success (IGA score, 0 or 1 and/or at least a 2-point reduction in IGA score) after 4 weeks. Secondary efficacy endpoints included a percentage reduction of total lesions and a change in total, inflammatory, and non-inflammatory lesions after 4 weeks.
Results: After 4 weeks, the proportion of patients achieving treatment success in the Siracilt™ Acne group was 65%; while it was 0%, 10%, and 0% in azelaic acid 10%, azelaic acid 20%, and clindamycin 1% groups, respectively. The percentage reduction in the number of total acne lesions after 4 weeks was 62.1%, 27.2%, 46.6%, and 25.1% with Siracilt™ Acne cream, azelaic acid 10% cream, azelaic acid 20% cream, and clindamycin 1% gel, respectively. Similar results were observed for change in total, inflammatory, and non-inflammatory lesions after 4 weeks. Overall, the treatments were safe and well tolerated.
Conclusions: In conclusion, Siracilt™ Acne cream demonstrated superior efficacy compared to azelaic acid and clindamycin in the treatment of mild to moderate acne vulgaris.

Keywords: Acne vulgaris, Azelaic acid, Clindamycin, Lactoferrin, Niacinamide, Siracilt™

INTRODUCTION

Acne vulgaris is a chronic inflammatory skin condition of the pilosebaceous unit affecting adolescents and young adults. It presents as non-inflammatory lesions (open or closed comedones) or inflammatory lesions (papules, pustules, or nodules). The multifactorial etiopathogenetic factors of acne vulgaris include follicular hyperkeratinisation, microbial colonization (with *Propionibacterium acnes*), sebum production, and complex inflammatory and neuroendocrine mechanisms. The mainstay of treatment for mild to moderate acne vulgaris is topical therapies, which include benzoyl peroxide (BP), retinoids, antibiotics, clascoterone, salicylic acid, and azelaic acid.[1]

Lactoferrin, an innate iron-binding protein, is present in exocrine secretions such as milk, tears, etc. Biological functions of lactoferrin include iron homeostasis, cellular growth and differentiation, anti-inflammatory activity, and

host defence against pathogens and cancer.[2] Despite potential activities against inflammation and microbial infection shown in preclinical studies, there is a paucity of literature evaluating lactoferrin in humans.[3-5] Though few studies have explored lactoferrin as oral supplementation, there is no literature available in knowledge evaluating topical lactoferrin treating mild to moderate acne vulgaris.[6-8]

Therefore, this pilot study was planned to evaluate and compare the efficacy and safety of Siracilt™ Acne cream (containing lactoferrin, azelaic acid, and niacinamide) against established treatments (azelaic acid cream and clindamycin gel) in the treatment of mild to moderate acne vulgaris.

METHODS

Study design

This randomized, open-label, active-controlled, parallel-group, single-center, comparative study was conducted (Mar-2024 to May-2024) at Namostute Hospital, Gandhinagar, India after obtaining approval from the institutional ethics committee (at Shasvat Surgicare Hospital, Gandhinagar, India). The study was conducted as per the study protocol in accordance with the good clinical practice guidelines of the International Council for Harmonisation, ethical guidelines by ICMR, and other applicable Indian regulations. It was registered prospectively on CTRI (registration no. CTRI/2024/01/061604). The written informed consent was obtained from all the patients before participation in the study.

Study population

Eligible patients of either gender aged between 18 to 65 years with mild to moderate acne vulgaris as determined by investigator global assessment (IGA) score of 2 or 3 were considered.

Patients with the use of topical acne medication within the last 1 week, known hypersensitivity reaction to any of the study medications, or any significant dermatological or any other systemic illness/condition that may interfere with the integrity of the study were excluded.

Treatment group

After confirmation of eligibility, eighty patients were randomized in a 1:1:1:1 manner into four groups: group 1, Siracilt™ Acne cream (containing lactoferrin 1%, azelaic acid 10% and niacinamide 2%) (manufacturer: Enavant Research LLP); group 2, azelaic acid 10% cream (Aziderm® 10%, Micro Lab); group 3, azelaic acid 20% cream (Aziderm® 20%, Micro Lab); and group 4, clindamycin 1% gel (Clindac A 1% from Alkem Labs). All trial medications were used as topical application as a thin layer to the affected area(s) of the skin for 4 weeks.

Study assessments

IGA scale was used in the study with scores ranging from 0 (clear), 1 (almost clear), 2 (mild), 3 (moderate), or 4 (severe).[9] The primary endpoint was the proportion of patients who achieved treatment success (IGA score, 0 or 1 and/or at least a 2-point reduction in IGA score) after 4 weeks. The secondary efficacy endpoints are mean percentage reduction in the number of acne lesions (papules, pustules, and nodules), change from baseline in total, inflammatory and non-inflammatory (open and closed comedones) lesions. The safety endpoint included the adverse events reported during the study.

There was a total of four visits: screening visit (3 days before randomization), baseline visit (day 1), follow-up visit (day, 14, week 2), and end-of-treatment/study visit (day 28, week 4).

Statistical analysis

Considering the pilot nature of the study, there was no formal hypothesis planned. Approximately 80 patients were planned to be randomized to obtain 64 evaluable patients considering 20% drop-out. Statistical test (such as Chi-square or Fisher's exact test) was considered to compare the success rates between the treatment groups. T-tests or Wilcoxon rank-sum tests were considered for secondary efficacy endpoints (total, inflammatory, and non-inflammatory lesions). All statistical tests were performed using two-sided tests at alpha 0.05 (95% confidence level), wherever applicable. The statistical analysis was performed using SAS software version 9.4 or higher (SAS Institute Inc., Cary, NC, USA).

RESULTS

A total of 80 patients were screened and randomized in this study. All patients completed the study (Figure 1).

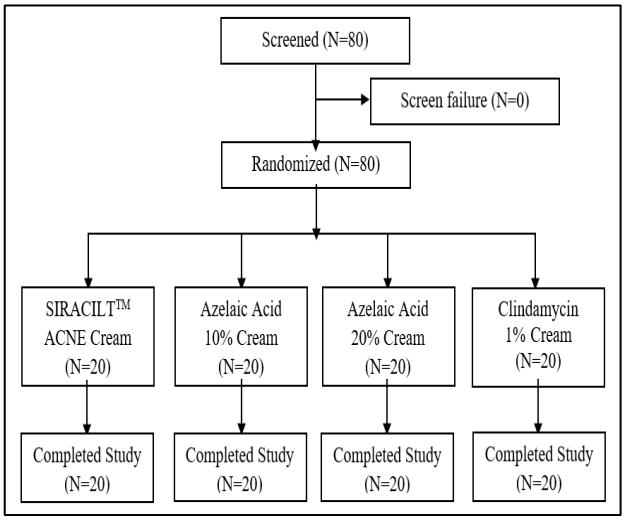

Figure 1: Study flow chart.

Table 1: Baseline characteristics.

Parameters	Siracilt™ Acne cream (n=20)	Azelaic acid 10% cream (n=20)	Azelaic acid 20% cream (n=20)	Clindamycin 1% gel (n=20)
Age (years)	27.75±9.66	27.05±11.16	27±9.77	25.40±7.86
Height (cm)	155.40±5.01	155.50±5.79	156.15±5.02	156±7.86
Weight (kg)	63.05±11.37	60.58±11.49	60.21±10.85	58.99±9.07
Gender				
Male [n (%)]	13 (65)	12 (60)	17 (85)	17 (85)
Female [n (%)]	7 (35)	8 (40)	3 (15)	3 (15)
Pulse rate (beats/minute)	78.55±5.53	81.35±4.77	80.05±4.81	80.8±4.07
Body temperature (°F)	98.39±0.46	98.32±0.52	98.48±0.49	98.52±0.47
Systolic blood pressure (mmHg)	123.6±4.47	123±3.86	123.1±4.32	124.1±5.40
Diastolic blood pressure (mmHg)	80.1±4.56	79.6±4.96	79.1±4.32	81.7±5.40
Respiratory rate (breaths/minute)	17.1±2.46	17.2±2.44	17±2.49	17.05±2.54

SD, standard deviation; kg, kilogram; cm, centimeter. N, number of subjects in a particular group; n, number of subjects in a specified category. All data (except gender) are presented as mean±SD.

Table 2: IGA scoring and proportion of patients achieving treatment success after 4 weeks.

IGA score	Siracilt™ Acne cream (n=20) (%)	Azelaic acid 10% cream (n=20) (%)	Azelaic acid 20% cream (n=20) (%)	Clindamycin 1% gel (n=20) (%)
0 = Clear	0 (0)	0 (0)	0 (0)	0 (0)
1 = Almost clear	13 (65)	0 (0)	2 (10)	0 (0)
2 = Mild	7 (35)	10 (50)	17 (85)	11 (55)
3 = Moderate	0 (0)	10 (50)	1 (5)	9 (45)
4 = Severe	0 (0)	0 (0)	0 (0)	0 (0)
Treatment success*	13 (65)	0 (0)	2 (10)	0 (0)
P value (between-group)	<0.01†‡§	-	-	-

*Treatment success is defined as an IGA score, of 0 or 1 and/or at least a 2-point reduction in IGA score.
†P value for comparison of treatment success between Siracilt™ Acne cream and azelaic acid 10% cream,
‡P value for comparison of treatment success between Siracilt™ Acne cream and Azelaic acid 20% cream,
§P value for comparison of treatment success between Siracilt™ Acne cream and Clindamycin 1% gel.
Data is presented as n (%), where n is the number of observations in a particular category, and % is derived by dividing n by the total number in the group (N).

Baseline characteristics

Overall, the baseline characteristics at screening were comparable in both groups (Table 1).

Primary endpoint

The proportion of patients who achieved treatment success after 4 weeks were 65%, 0%, 10%, and 0% in the Siracilt™ Acne, azelaic acid 10%, azelaic acid 20%, and clindamycin 1% groups, respectively (Table 2).

Secondary endpoints

Total, inflammatory, and non-inflammatory lesions were comparable at baseline across the groups. There was a significant reduction in total lesions in all groups after 4 weeks; the reduction in total lesions was superior with Siracilt™ Acne (-34.7, 62.13%) compared to azelaic acid 10% (-15.35, 27.24%), azelaic acid 20% (-26.25, 46.58%) and clindamycin 1% (-14.15, 25.11%). Similar results were observed in the reduction of inflammatory and non-inflammatory lesions (Table 3).

Safety

Overall, a total of 23 adverse events (20 mild and 3 moderate) were reported in the study. The causality assessment was reported as probable for eight adverse events and unlikely for the remaining 15 adverse events. The most common AEs were itching, body pain, cold, headache, and redness (Table 4). All events recovered/ resolved without any sequelae. There were no serious adverse events or adverse events requiring discontinuation during the study.

Table 3: Total, inflammatory and non-inflammatory lesions after 4 weeks.

	Siracilt™ Acne cream (n=20)	Azelaic acid 10% cream (n=20)	Azelaic acid 20% cream (n=20)	Clindamycin 1% gel (n=20)
Inflammatory lesions				
Baseline	27.05±5.52	25.90±5.72	26.25±5.30	26.45±6.31
4 Weeks	10.70±4.66	19.35±5.34	14.80±4.76	20.75±5.87
Reduction in the number of lesions (%)	60.44	25.29	43.62	21.55
Change from baseline	-16.35±0.86	-6.55±0.38	-11.45±0.54	-5.7±0.44
P value (within the group)	<0.01	<0.01	<0.01	<0.01
P value (between-group)	<0.01*†‡	-	-	-
Non-inflammatory lesions				
Baseline	28.80±5.01	30.45±5.79	30.10±5.43	29.90±5.62
4 Weeks	10.45±4.35	21.65±5.95	15.30±4.57	21.45±5.23
Reduction in the number of lesions (%)	63.71	28.88	49.17	28.26
Change from baseline	-18.35±0.66	-8.8±0.16	-14.8±0.86	-8.45±0.39
P value (within the group)	<0.01	<0.01	<0.01	<0.01
P value (between-group)	<0.01*†‡	-	-	-
Total lesions				
Baseline	55.85±8.69	56.35±9.87	56.35±9.71	56.35±10.09
4 Weeks	21.15±8.41	41.00±9.58	30.10±8.41	42.20±9.49
Reduction in the number of lesions (%)	62.13	27.24	46.58	25.11
Change from baseline	-34.7±0.28	-15.35±0.29	-26.25±1.3	-14.15±0.6
P value (within the group)	<0.01	<0.01	<0.01	<0.01
P value (between-group)	<0.01*†‡	-	-	-

*P value for comparison of change from baseline in lesions between Siracilt™ Acne cream and Azelaic acid 10% cream,
†P value for comparison of change from baseline in lesions between Siracilt™ Acne cream and Azelaic acid 20% cream,
‡P value for comparison of change from baseline in lesions between Siracilt™ Acne cream and Clindamycin 1% gel.
Data is presented as mean±SD unless specified otherwise.

Table 4: Adverse events reported during the study.

Adverse event term	Siracilt™ Acne cream (n=20)	Azelaic acid 10% cream (n=20)	Azelaic acid 20% cream (n=20)	Clindamycin 1% gel (n=20)
Body Pain	-	2	-	1
Cold	2	1	-	-
Diarrhea	-	-	-	1
Dryness	-	-	-	1
Fever	1	1	-	-
Headache	1	-	2	-
Itching	2	1	1	1
Nausea	-	1	1	-
Redness	1	1	1	-

DISCUSSION

Topical therapies like benzoyl peroxide, retinoids, and antibiotics are the mainstay of treatment for mild to moderate acne vulgaris; however, safe and effective treatment options are urgently needed to address increasing rates of antibiotic resistance and side effects from current treatments. Siracilt™ Acne cream is a novel treatment alternative combining lactoferrin, azelaic acid, and niacinamide. Lactoferrin, an innate protein found in milk, has demonstrated activities against inflammation and microbial infection in preclinical studies.[3-5] Azelaic acid is a topical comedolytic, antibacterial, and anti-inflammatory agent, preferred for patients with sensitive skin or darker skin types. Azelaic acid is proven as an effective monotherapy in mild to moderate acne, with an overall efficacy comparable to that of 0.05% tretinoin, 5% benzoyl peroxide, and 2% topical erythromycin.[10] Topical nicotinamide, a vitamin, plays a potential role in acne vulgaris by significantly reducing sebum excretion rate and decreasing casual sebum levels on the skin surface, as well as inhibiting *P. acnes*-induced IL-8 production in keratinocytes without the risk of bacterial resistance and systemic side effects.[11,12] Multiple studies have demonstrated that niacinamide offers a significant reduction in acne lesions similar to clindamycin.[13-15]

This randomized, open-label, active-controlled, parallel-group, single-center, comparative pilot study was planned to evaluate the efficacy and safety of a Siracilt™ Acne cream and compare it against established treatments (azelaic acid cream and clindamycin gel) in patients with mild to moderate acne vulgaris. The proportion of patients achieving treatment success after 4 weeks of Siracilt™ Acne cream administration was significantly better than azelaic acid creams 10% and 20%, and clindamycin 1% gel. Further, the reduction in total, inflammatory, and non-inflammatory lesions was significantly better with Siracilt™ Acne cream than with the other three groups. As expected, Siracilt™ Acne cream was well tolerated in the present study population considering the safe nature of ingredients.

Kim et al evaluated the efficacy of 200 mg of lactoferrin with fermented milk containing probiotics in patients with mild to moderate acne vulgaris.[16] After 12 weeks of once-daily treatment, the percentage reduction in inflammatory and total lesions were 69.8% and 56.3% respectively. The present study observed a similar reduction after 4 weeks at 60.44% and 62.13% in inflammatory and total lesions, respectively. Mueller et al evaluated the efficacy of 200 mg (twice daily administration of chewable 100 mg tablets) lactoferrin in a single-arm, exploratory study; and after 8 weeks of administration, mean improvements in lesion counts (inflammatory, non-inflammatory, and total) ranged from 20.2 to 23.5%.[7] In another study conducted by Chan et al evaluating oral lactoferrin 200 mg with vitamin E and zinc, the reduction of total and inflammatory lesions at 4 weeks were approximately 25% and 35%, respectively.[8] The indirect comparison may not be appropriate due to many differences (in terms of baseline lesion count, route of administration, assessment timepoint, etc) between these studies and the present study. However, a substantial and comparable reduction of lesion count offers proof of the efficacy of topical administration of lactoferrin as an adjunct to azelaic acid and niacinamide.

In the present study, azelaic acid 10% and 20% were selected as comparators to provide a direct comparison with Siracilt™ Acne cream which also contains azelaic acid 10%. As expected, 20% azelaic acid has better efficacy compared to 10% azelaic acid. In a placebo-controlled study conducted by Iraji et al, treatment with azelaic acid 20% gel resulted in ≈60% reduction in total lesions compared to 20% in the placebo group.[17] In a study conducted by Tabari et al, azelaic acid 20% cream and clindamycin 1% lotion provided approximately 30% reduction in total lesions after one month of treatment.[18] The present study has similar results observed with clindamycin 1% gel; however, the reduction in azelaic acid was slightly higher at 49.17%.

There were strengths and limitations of the present study. To our knowledge, this is the first randomized trial to date evaluating the effectiveness of a topical combination containing lactoferrin, azelaic acid, and niacinamide in the treatment of acne. The study was designed as a pragmatic trial to inform real-world decision-making and to reflect the potential role of topical lactoferrin in the clinical pathway. The study was planned as a pilot study with a limited sample size at a single center; therefore, the generalization of results warrants careful consideration. Due to the relatively objective nature of the assessment, the open-label study design was considered; however, the bias due to treatment awareness cannot be completely ignored. Further, the treatment duration was only four weeks; therefore, long-term clinical trials are warranted to provide valuable insights on the potential increase or decrease in efficacy over a longer time frame.

CONCLUSION

This pilot clinical study demonstrated that Siracilt™ Acne cream (containing lactoferrin, azelaic acid, and niacinamide) provides superior efficacy compared to azelaic acid cream and clindamycin gel in the treatment of mild to moderate acne vulgaris. Lactoferrin-based cream may serve as a safe and effective treatment for managing mild to moderate acne vulgaris.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was registered prospectively on CTRI (registration no. CTRI/2024/01/061604)

REFERENCES

1. Reynolds RV, Yeung H, Cheng CE, Cook-bolden F, Desai SR, Druby KM, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024;90(5):1006.e1-e30.
2. Ward PP, Paz E, Conneely OM. Multifunctional roles of lactoferrin: a critical overview. Cell Mol Life Sci. 2005;62(22):2540-8.
3. Håversen H, Ohlsson BG, Hahn-Zoric M, Hanson LA, Mattsby-Baltzer I. Lactoferrin down-regulates the LPS-induced cytokine production in monocytic cells via NF-kappa B. Cell Immunol. 2002;220(2):83-95.
4. Machnicki M, Zimecki M, Zagulski T. Lactoferrin regulates the release of tumour necrosis factor alpha and interleukin 6 in vivo. Int J Exp Pathol. 1993;74(5):433-9.
5. Crouch SP, Slater KJ, Fletcher J. Regulation of cytokine release from mononuclear cells by the iron-binding protein lactoferrin. Blood. 1992;80(1):235-40.
6. Kim J, Ko Y, Park YK, Kim NI, Ha WK, Cho Y. Dietary effect of lactoferrin-enriched fermented milk on skin surface lipid and clinical improvement of acne vulgaris. Nutrition. 2010;26(9):902-9.
7. Mueller EA, Trapp S, Frentzel A, Kirch W, Brantl V. Efficacy and tolerability of oral lactoferrin supplementation in mild to moderate acne vulgaris: an exploratory study. Curr Med Res Opin. 2011;27(4):793-7.
8. Chan H, Chan G, Santos J, Dee K, Co JK. A randomized, double-blind, placebo-controlled trial to determine the efficacy and safety of lactoferrin with

vitamin E and zinc as an oral therapy for mild to moderate acne vulgaris. Int J Dermatol. 2017;56(6):686-90.
9. Guidance for Industry. Acne Vulgaris: Developing Drugs for Treatment. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), September 2005. Available from: https://downloads.regulations.gov/FDA-1975-N-0012-0317/attachment_250.pdf. Accessed on 3 July 2025.
10. Graupe K, Cunliffe WJ, Gollnick HP, Zaumseil RP. Efficacy and safety of topical azelaic acid (20 percent cream): an overview of results from European clinical trials and experimental reports. Cutis. 1996;57(1):20-35.
11. Draelos ZD, Matsubara A, Smiles K. The effect of 2% niacinamide on facial sebum production. J Cosmet Laser Ther. 2006;8(2):96-101.
12. Grange PA, Raingeaud J, Calvez V, Dupin N. Nicotinamide inhibits Propionibacterium acnes-induced IL-8 production in keratinocytes through the NF-kappaB and MAPK pathways. J Dermatol Sci. 2009;56(2):106-12.
13. Shalita AR, Smith JG, Parish LC, Sofman MS, Chalker DK. Topical nicotinamide compared with clindamycin gel in the treatment of inflammatory acne vulgaris. Int J Dermatol. 1995;34(6):434-7.
14. Khodaeiani E, Fouladi RF, Amirnia M, Saeidi M, Karimi ER. Topical 4% nicotinamide versus 1% clindamycin in moderate inflammatory acne vulgaris. Int J Dermatol. 2013;52(8):999-1004.
15. Shahmoradi Z, Iraji F, Siadat AH, Ghorbaini A. Comparison of topical 5% nicotinamid gel versus 2% clindamycin gel in the treatment of the mild-moderate acne vulgaris: a double-blinded randomized clinical trial. J Res Med Sci. 2013;18(2):115-7.
16. Kim J, Ko Y, Park YK, Kim NI, Ha WK, Cho Y. Dietary effect of lactoferrin-enriched fermented milk on skin surface lipid and clinical improvement of acne vulgaris. Nutrition. 2010;26(9):902-9.
17. Iraji F, Sadeghinia A, Shahmoradi Z, Siadat AH, Jooya A. Efficacy of topical azelaic acid gel in the treatment of mild-moderate acne vulgaris. Indian J Dermatol Venereol Leprol. 2007;73(2):94-6.
18. Tabari ST, Nia AAM, Hajian K, Moeinzadeh A. Comparison of the effect of azelaic acid 20% and clindamycin 1% in the treatment of mild and moderate acne. Iran J Dermatol. 2009;12:106-10.

Cite this article as: Shah HJ, Pariyani JK, Shinde KV. Efficacy and safety of lactoferrin based cream (Siracilt™ acne) in the treatment of patients with mild to moderate acne vulgaris – a randomized, comparative and pilot study. Int J Basic Clin Pharmacol 2025;14:983-8.