

**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.**

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**Abstract**

*Background:* Lactoferrin is an iron-binding milk-derived protein that has shown antibacterial and anti-inflammatory effects *in vitro* and *in vivo*. The objective of this study was to determine the efficacy and safety of lactoferrin, combined with vitamin E and zinc, for mild to moderate acne vulgaris.

*Methods:* In this randomized, double-blind, placebo-controlled trial, 168 subjects aged 13-40 years old were randomly assigned to take either a capsule formulation containing lactoferrin with vitamin E and zinc or placebo twice a day for 3 months. The primary outcome measure was a reduction in the number of acne lesions compared to placebo.

*Results:* One hundred sixty-four subjects completed the study per protocol. The lactoferrin group (n=82) showed a significant median percent reduction of total lesions as early as 2 weeks (14.5%, p=0.0120), with the maximum reduction occurring at week 10 (28.5%, p<0.0001) compared to placebo group (n=82). Maximum reduction in comedones (32.5%, p<0.0001) and inflammatory lesions

(44%,  $p < 0.0001$ ) were also seen at week 10 compared to placebo. Sebum scores improved by week 12. No adverse events were observed during the trial.

*Conclusions:* A twice daily regimen of lactoferrin with vitamin E and zinc significantly reduced acne lesions in people with mild to moderate acne vulgaris.