

Assessment of the Effectiveness and Safety of Test Toothpaste for Overall Oral Health in Diabetic Patients: An Open-label, Single-arm, Multicenter Clinical Trial



The safety and efficacy of a test product for comprehensive oral care in individuals with diabetes were evaluated through an open-label, single-arm, multicentric clinical study. Both male and female subjects participated, comprising 31 (62%) males and 19 (38%) females. Subjects were instructed to brush their teeth twice daily for 2 minutes using a soft brush and a pea-sized amount of the test toothpaste, equivalent to approximately one bristle length of the product. This regimen was followed for a duration of 90 days, with brushing sessions occurring once in the morning before breakfast and again at night before sleeping.

The study aimed to determine several outcomes. Firstly, it assessed the non-worsening of buccal irritation scoring from baseline to the end of study (EOS) to ensure the safety of the toothpaste. Subjects were also closely monitored for any adverse events related to oral health, with no adverse events reported throughout the study.

Furthermore, the efficacy of the test product was evaluated through various parameters. These included supporting periodontal health using Russell's periodontal index, improving hydration in the oral cavity measured by the Schirmer test, reducing plaque buildup as assessed by the Loe & Silness Plaque index, and decreasing gum inflammation through the Loe & Silness Gingival index. Additionally, the study examined the reduction in mouth odor, provision of mouth freshness, and achievement of a clean and healthy mouth feel using the Organoleptic scale.

Finally, the study explored the suitability of the test product for providing comprehensive oral care in individuals with diabetes through a subjective self-assessment questionnaire. Efficacy assessments encompassed Russell's periodontal index, the Schirmer test, the plaque index, the gingival index, and the Organoleptic scale. Overall, the study aimed to provide comprehensive insights into the safety and efficacy of the test product in managing oral health in diabetic individuals.