

NCT04901507

Effects of an External Oral Irrigation Device on Patients With Dry Mouth

07/01/2021

Statistical Analysis Plan

The responses from the OHIP -14 and XI surveys are scored on a five-point scale (OHIP-14: 0-4, XI: 1-5). The examiner scores the features observed in the patient's mouth and derives a COD score of 0-10. Clinical findings observed are given a one-point value for CODS, with 10 indicating the most severe oral dryness.

Unstimulated salivary flow (USSF) will be tested prior to stimulated flow to enhance accuracy. USSF is measured using a Schirmer strip placed on the floor of the mouth with the patient seated upright. Next, the patient is given unflavored wax to chew and is instructed to expectorate into a medicine cup for three minutes to yield the stimulated salivary flow (SSF).

Scores will be compared before and after use of the device with paired t-tests, assuming data demonstrates normal distribution. If not, nonparametric alternatives will be utilized. SAS EG v.8.2 (SAS Institute, Cary, NC) will be used for all analyses. Significance level is set at 0.05.