

## MucoDry X Randomized, double-blind, placebo controlled, study - Ship JA et al., (2007).

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal
Ship JA et al., (2007).	Randomized, double blind, placebo controlled, study	40 dry mouth patients	Xerostom® rinse, spray and gel (olive oil, betaine and xylitol)	Products are safe and effective in relieving symptoms of dry mouth	No	D2 A1 P1 R1 T1 O1 F1 S1 C1

### CASP Questions for making sense of evidence

1. Did the study ask a clearly focused question?	2. Was this a RCT, and was it appropriately so?	3. Were participants appropriately allocated to intervention and control groups?	4. Were participant, staff, and study personnel blinded to participants' study group?	5. Were all participants who entered the trial accounted for at its conclusion?	6. Were the participants in all groups followed up and data collected in the same way?	7. Did the study have enough participants to minimize the play of chance?	8. How are the results presented, and what is the main result?	9. How precise are these results?	10. Were all important outcomes considered so that the results can be applied?
Yes	Yes. Appropriate for this study	Yes. Participants randomly assigned to xylitol containing spray and gel or placebo for 1 week.	Yes	Yes. 40 patients with dry mouth	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	Statistically significant differences between control and Xerostom (olive oil, betaine and xylitol) in overall mouth dryness (p= 0,038), overall tongue dryness (p= 0,002) and level of thirst (p= 0,001) favouring Xerostom® group.	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

## **Synopsis - Randomized, double-blind, placebo controlled, study - Ship JA et al., (2007).**

Ship JA et al., (2007) evaluated the safety and efficacy of a group of topical dry mouth products (toothpaste, mouth rinse, mouth spray and gel) containing olive oil, betaine and xylitol in a randomized, single-blinded, controlled, cross-over clinical study in 40 adults (aged 50-67 years) for one week. Subjects were randomly assigned at baseline to using the novel topical dry mouth products containing olive oil, betaine and xylitol (Xerostom®) daily for 1 week, or to maintain their normal dry mouth routine care. After 1 weeks, they were crossed over to the other dry mouth regimen. There were evaluated 8 aspects of xerostomia and found statistically significant differences between control and Xerostom (olive oil, betaine and xylitol) in overall mouth dryness ( $p=0,038$ ), overall tongue dryness ( $p=0,002$ ) and level of thirst ( $p=0,001$ ) favouring Xerostom® group.

The Visual Analogue Scale (VAS) showed statistically significant improvements in the dryness of the mouth and tongue and a decrease in thirst when using Xerostom® products as compared with their normal dry mouth routine.

The results demonstrated that the use of the novel topical dry mouth products increased significantly unstimulated whole salivary flow rates, reduced complaints of xerostomia and improved xerostomia-associated quality of life. No clinically significant adverse events were observed.

Authors concluded that the daily use of topical dry mouth products containing olive oil, betaine and xylitol is safe and effective in relieving symptoms of dry mouth in a population with polypharmacy-induced xerostomia.