

## **MucoDry X    Randomized, double-blind, crossover study - Morales-Bozo I et al., (2012)**

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal
Morales-Bozo I et al., (2012)	Randomized, double-blind, crossover study	67 dry mouth patients	2 rinses containing of xylitol, , glycerine and citric acid.	Both mouthrinses were effective in relieving various xerostomia symptoms	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 rinse 1 containing xylitol or rinse 2 containing glycerine, xylitol, citric acid for 2 weeks	Yes	Yes. 67 patients with xerostomia	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	Both rinses relieved the sensation of dry mouth, the need to drink liquids to swallow and the difficulty in swallowing food, improved the quality of life	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

## **Synopsis - Randomized, double-blind, crossover study - Morales-Bozo I et al., (2012)**

Morales-Bozo I et al., (2012) evaluated the efficacy of two mouthrinses in the reduction of xerostomía-associated symptomatology in a randomized, double-blind, cross-over clinical trial with progressive recruitment and a washout period, in 67 adult patients with xerostomia of diverse origin. The median unstimulated salivary flow in the study sample was 0,230 ml/min with a range from 0,04 to 0,982 ml/min.

Rinse 1 was composed principally of an aqueous solution containing xylitol, sodium fluoride, cetylpyridinium chloride, sodium chloride and spearmint flavouring. Rinse 2 was composed of the same components as rinse 1, with the addition of propylene glycol, aloe vera, glycerine and citric acid.

On day 1, half of the patients (n = 34, group A) started the study using rinse 1 and the other half (n = 33, group B) started the study using rinse 2. Patients used the appropriate solution for 7 days. Later, there was a 4-day washout period, in which the patients were instructed to suspend the use of the rinses. On day 13, the order of the mouthrinses administered to the patients was inverted, and the patients used the rinses for seven more days. At the beginning of days 1 and 13 of the study, a survey determining the xerostomia baseline was performed to evaluate the severity of xerostomia before the use of the rinse being tested.

Both groups of patients were compared with each other with regard to the magnitudes of sensation of dry mouth, sensation of thick saliva, burning tongue, need to drink liquids to swallow and difficulty in swallowing food, both before and after the use of the rinse. In the group of patients displaying one xerostomia-associated pathology (n = 48), rinse 1 relieved only the sensation of dry mouth, in contrast to its effect among patients displaying 2 or more xerostomia-associated pathologies (n = 19) among which it relieved the need to drink liquids to swallow and the difficulty in swallowing food.

Rinse 2 relieved the need to drink liquids to swallow and the difficulty in swallowing food only among patients displaying 2 or more associated pathologies.

Authors concluded that both rinses were more effective in relieving xerostomia-associated symptomatology in patients taking 3 or more medicines simultaneously.