

## MucoDry X    Randomized, placebo controlled, double-blind study - Femiano F et al., (2011)

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal
Femiano F et al., (2011)	Randomized, double-blind, placebo controlled, parallel study	54 dry mouth patients	A salivary substitute vs citric acid	Citric acid provided a longer-lasting feeling of oral moistness	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 saliva substitutes and citric acid or placebo, during 30 days	Yes	Yes. 54 patients with drug-induced xerostomia	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	Significant improvement on dry mouth symptoms: one hour after solution intake, 7 patients (39%) from the artificial saliva group, 10 (56%) from the citric acid group, and 0 from the water.	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

## **Synopsis - Randomized, placebo controlled, double-blind study - Femiano F et al., (2011)**

Femiano F et al., (2011) compared in a randomized, double blind, placebo controlled, parallel study the efficacy of saliva substitutes and citric acid long-term therapy for oral dryness relief and unstimulated salivary flow in patients reporting drug-induced xerostomia.

54 patients reporting drug-induced xerostomia were randomly subdivided into 3 groups and respectively administered artificial saliva, 3% citric acid, or distilled water in mouthwash 4 times a day for 30 days. The patients in group 1 received a salivary substitute (containing water, hydroxypropyl cellulose, sorbitol, dipotassium chloride, sodium chloride, magnesium chloride, calcium chloride, and potassium phosphate) with a neutral pH (~7) and were marked as the artificial saliva group. The patients in group 2 received a solution of citric acid (3% in essential water) with pH of ~3,5 and were marked as the citric acid group. The patients in group 3 received distilled water with a pH of 7 and were marked as the water group.

Patients underwent measurement of unstimulated whole saliva before and after they finished therapy and were asked to note in a daily diary any symptomatologic changes 15 minutes and 1 hour after each daily intake of test solution.

Fifteen minutes after solution intake, 12 patients (67%) belonging to the artificial saliva group, 9 (50%) from the citric acid group, and 2 (11%) from the water group reported significant symptomatologic improvement. One hour after solution intake, 7 patients (39%) from the artificial saliva group, 10 (56%) from the citric acid group, and 0 from the water group noted significant symptomatologic improvement. None of the drugs tested affected unstimulated whole saliva flow.

The medicaments used for the study were well tolerated, and no patient noted serious adverse effects in their diaries.

Authors concluded that both artificial saliva and citric acid provided immediate relief from oral dryness. Citric acid also provided a longer-lasting feeling of oral moistness at 1 hour after use owing to its protracted activity on salivary gland function.