

## **MucoDry X    Randomized, controlled clinical trial - Silvestre FJ et al., (2009)**

<b>Authors (year published)</b>	<b>Study design</b>	<b>Total patients</b>	<b>Intervention</b>	<b>Reported outcomes/results</b>	<b>Adverse events</b>	<b>Appraisal</b>
Silvestre FJ et al., (2009)	Randomized, controlled clinical trial	37 dry mouth patients	Spray containing mineral salts, xylitol and citric acid	Application of the spray is simple and effective, affording immediate relief of dry mouth symptoms	No	D2 A1 P1 R1

### **CASP Questions for making sense of evidence**

<b>1. Did the study ask a clearly focused question?</b>	<b>2. Was this a RCT, and was it appropriately so?</b>	<b>3. Were participants appropriately allocated to intervention and control groups?</b>	<b>4. Were participant, staff, and study personnel blinded to participants' study group?</b>	<b>5. Were all participants who entered the trial accounted for at its conclusion?</b>	<b>6. Were the participants in all groups followed up and data collected in the same way?</b>	<b>7. Did the study have enough participants to minimize the play of chance?</b>	<b>8. How are the results presented, and what is the main result?</b>	<b>9. How precise are these results?</b>	<b>10. Were all important outcomes considered so that the results can be applied?</b>
Yes	Yes. Appropriate for this study	Yes. Participants randomly assigned to artificial saliva in spray form containing an aqueous solution of mineral salts, xylitol and citric acid or no treat, during 7 days	Yes	Yes. 37 elderly patients with dry mouth	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	Twenty of the 37 patients showed almost immediate improvement after application. In 90% of the cases the duration of the effect was 10 minutes or more, while in 65% of the cases the effect lasted for 15 minutes or more.	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

## **Synopsis - Randomized, controlled clinical trial - Silvestre FJ et al., (2009)**

Silvestre FJ et al., (2009) demonstrated in a randomized, controlled clinical study the subjective improvement afforded by a new artificial saliva in spray form containing an aqueous solution of mineral salts, xylitol and citric acid, in 37 elderly patients (aged over 60 years) with dry mouth, for 7 days. All the patients (n=37) selected for this study presented some antecedent of disease characteristic of the age involved. All patients presented hyposialia as confirmed by resting whole saliva (RWS) <0.1 ml/min and stimulated whole saliva (SWS) <0.7 ml/min.

A new artificial saliva in spray format was applied, with evaluation of the degree of improvement (VAS scale), frequency of application, time to improvement in minutes, duration in minutes, and assessment of organoleptic properties. All the patients applied the product at least twice a day, and a maximum of 7 times a day (mean 3,89 daily applications). A total of 54% of the patients used the spray three or four times a day.

Twenty of the 37 patients showed almost immediate improvement after application. Twenty patients (54%) reported some improvement after using the spray. Such improvement was immediate in 19 cases, while one patient reported improvement after one minute. The duration of the humidification effect ranged from 6-28 minutes, with an average of 15,3 minutes. In 90% of the cases the duration of the effect was 10 minutes or more, while in 65% of the cases the effect lasted for 15 minutes or more. There was no relationship between such improvement and the background disease or drug use. No adverse effects were associated with the use of the product.

Authors concluded that application of the spray is simple and effective, affording immediate relief, and with reasonable acceptance among patients with dry mouth.