MucoDry X Randomized, double-blind, crossover study - Jellema AP et al., (2001)

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal
Jellema AP et al., (2001)	Randomized, double-blind, placebo-controlled crossover clinical trial.	30 dry mouth patients	Xialine® (xanthan gum) saliva substitute spray	Xerostomia in general decreased with both Xialine® and placebo to almost the same degree.	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 xanthan gum or placebo, for 3 weeks	Yes	Yes. 30 patients with radiation-induced xerostomia	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	The response rate for both scales was 45% after using Xialine® compared to 21 and 24%, respectively, after using placebo.	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

Synopsis - 2001 Randomized, double-blind, crossover study - Jellema AP et al., (2001)

Jellema AP et al., (2001) evaluated in a randomized, double blind, placebo controlled, crossover study the efficacy of Xialine® (xanthan gum) saliva substitute spray in 30 patients (aged 46-79 years) with radiation-induced xerostomia for 1 week per phase, overall 3 week. Changes in subjective sensations due to xerostomia before and after administration of Xialine® were evaluated.

Twenty-nine patients completed the study. In general, no differences were noted with regard to the baseline values of the analyzed scales on visit 1 and visit 3. Therefore, a 1 week washout period was considered to be sufficient. Xialine® was used with a mean frequency of 14 times a day, which was comparable to the frequency observed when the placebo was used (13 times per day). The order in which Xialine® and placebo were used did not affect the results.

Xerostomia in general decreased with both Xialine® and placebo to almost the same degree. A trend towards higher response rates after Xialine® was observed for problems with speech and decreased senses compared to placebo. The response rate for both scales was 45% after using Xialine® compared to 21 and 24%, respectively, after using placebo.

Authors concluded that xerostomia decreased with both Xialinew and placebo to almost the same degree. A trend was noted towards a higher degree of improvement of problems with speech and senses when Xialine® was used. However, the results do not support an additional value of xanthan gum-based saliva substitutes over other saliva substitutes among patients with radiation-induced xerostomia.