MucoDry X Randomized, placebo controlled, double-blind study - Van der Reijden WA et al., (1996)

Authors (year published)	Study design	Total patients	Intervention	Reported outcomes/results	Adverse events	Appraisal
Van der Reijden WA et al., (1996)	Randomized, placebo controlled, double-blind study	43 dry mouth patients	3 rinses Carbopol (polyacrylic acid), xanthan gum, saliva Orthana and placebo	Preference for a particular saliva substitute over placebo was equally distributed among the 3 types of substitutes.	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 assignned to 3 types of polymer-based saliva substitutes or placebo for 7 weeks.	Yes	Yes. 43 patients with primary and secondary Sjögren's syndrome	Safety and efficacy data obtained on all patients	Yes-power analysis performed.	Preference for a particular saliva substitute over placebo was equally distributed among the 3 types of substitutes.	Statistical tests appropriately used can have confidence in results.	Efficacy and safety both considered.

Synopsis - Randomized, placebo controlled, double-blind study - Van der Reijden WA et al., (1996)

Van der Reijden WA et al., (1996) examined in a randomized, double-blind, placebo-controlled trial the efficacy of 3 types of polymer-based saliva substitutes in reducing oral dryness in 43 patients (aged 25-79 years) with primary and secondary Sjögren's syndrome for total 7 week. Participants were randomly assigned to receive carbopol (polyacrylic acid) saliva substitute (group A), xanthan gum saliva substitute (group B), saliva Orthana (commercial prepared saliva substitute; group C) and placebo (group D). Products all used ad libitum for 1 week. Duration of intervention: 4 x 1-week test periods with 1-week washouts in between (total 7 weeks). Salivary flow rates (SFR) were determined to examine correlations between the salivary flow rates and the subjective efficacy of the saliva substitute.
Neither the saliva substitutes nor the placebo was truly effective. Preference for a particular saliva substitute over placebo was equally distributed among the 3 types of substitutes. The salivary flow rates of patients who preferred polyacrylic acid-based saliva substitutes was lower than that in patients who preferred the porcine mucin-based substitute ($p < 0,05$). Patients whose oral dryness was reduced by low-viscoelastic substitutes had a low stimulated salivary flow rates (< 0,20 ml/minute; $p < 0,05$).
No side effects from the saliva substitutes were observed during the study.
Authors concluded that the optimal properties of a saliva substitute are not the same for all patients with Sjögren's syndrome, but are dependent on such parameters as the individual salivary flow rates . Thus, to determine the best saliva substitute for a particular patient, it is necessary to have the patient try a number of substitutes of different viscoelastic properties.

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