A clinical study investigating the gingivitis efficacy of an anhydrous test dentifrice


Aim

To evaluate and compare the gingivitis efficacy of an anhydrous test dentifrice containing 0.454% w/w stannous fluoride for gingival health, against a sodium monofluorophosphate dentifrice (negative control) after 12 weeks of twice-daily use.

Study products and usage

- Anhydrous test dentifrice containing 0.454% stannous fluoride and the inactive ingredient 5% sodium tripolyphosphate (STP)
- Sodium monofluorophosphate (SMFP) dentifrice containing 1000ppm fluoride (Colgate Cavity Protection®)
- Subjects brushed twice-daily with a full brush head of their allocated study product

Methods

- Examiner-blind, two arm, randomized and stratified (by gender and baseline modified gingival index, MGI) clinical study in 107 healthy adult subjects with moderate gingivitis (as measured using the MGI).
- Eligible subjects who met the entry criteria underwent dental prophylaxis (with conventional dental prophylaxis paste) followed by flossing. Subjects were randomly assigned to one of two treatment groups: 48 subjects to the anhydrous test dentifrice containing 0.454% stannous fluoride group, 49 subjects to the sodium monofluorophosphate dentifrice group.
- Gingival health was measured in two ways; gingival bleeding index (BI)¹ and modified gingival index (MGI)², with supra-gingival plaque levels measured using the Turesky modification of the Quigley Hein plaque index²,³, both overall and interproximally, after 6 and 12 weeks’ treatment.

Results

- Results showed that subjects using the anhydrous test dentifrice demonstrated statistically significantly lower mean whole mouth gingival bleeding compared to those using the sodium monofluorophosphate dentifrice, after 12 weeks’ treatment, Figure 1.
- Statistically significant differences in favor of the anhydrous test dentifrice were also observed for all other measures (mean BI at week 6, Figure 1; mean MGI, Figure 2; and mean PI, Figure 3 at 6 and 12 weeks) compared to the sodium monofluorophosphate dentifrice.

Figure 1. Whole Mouth Mean Bleeding Index (BI)

- 0.454% stannous fluoride/5% STP dentifrice
- Sodium monofluorophosphate dentifrice

*p<0.0001
Dental prophylaxis was performed immediately after the baseline assessment. Bleeding index scores range from 0 (no bleeding, 30 seconds after probing) to 2 (immediate bleeding on probing).
Dental prophylaxis was performed immediately after the baseline assessment. Modified gingival index scores range from 0 (absence of inflammation) to 4 (severe inflammation).

Safety
107 subjects comprised the safety population, 12 subjects reported 15 treatment-emergent adverse events (TEAEs). Of these, 2 were classified as oral AEs (mouth ulceration in the anhydrous test dentifrice group; a tooth fracture in the control dentifrice group). The mouth ulceration was considered treatment related, and this subject was withdrawn from the study. All AEs were of mild intensity. No serious AEs were reported.

Conclusion
The anhydrous test dentifrice containing 0.454% stannous fluoride and the inactive ingredient 5% STP was statistically significantly superior to a sodium monofluorophosphate dentifrice in controlling gingivitis (gingival bleeding, BI) and visual signs of gingival inflammation (MGI), and supra-gingival plaque.

The magnitude of differences in BI, MGI and the plaque assessment observed in this study between the test and control treatments, 45%, 17.8% and 9.9% respectively, are in agreement with those published in the literature for 0.454% w/w stannous fluoride containing anti-gingivitis dentifrices after 12 weeks’ twice-daily brushing.

In the other efficacy analysis, after 12 weeks of twice-daily brushing, the proportion of sites that either decreased or demonstrated no change in BI was greater for the anhydrous test dentifrice than the sodium monofluorophosphate dentifrice. A reduction in the number of bleeding sites potentially represents a significant decrease in risk to future periodontal breakdown.

Both treatments were well tolerated.

References:

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