A clinical study investigating the gingivitis efficacy of a test dentifrice

GSK Data on File. RH01515, January 2014

Aim
- To evaluate and compare the gingivitis efficacy of an anhydrous test dentifrice containing 0.454% w/w stannous fluoride, against a fluoride dentifrice (negative control) after 24 weeks of twice-daily use

Study products and usage
- Anhydrous test dentifrice containing 0.454% stannous fluoride and 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 (gender and baseline modified gingival index, MGI) clinical study in 98 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: 43 subjects to the anhydrous test dentifrice containing 0.454% stannous fluoride, 48 subjects to the sodium monofluorophosphate dentifrice group
- 2 measurements for gingival health; gingival bleeding index (BI)\(^1\) and modified gingival index (MGI)\(^2\), with supra-gingival plaque levels measured by plaque index, (PI) (Turesky modification of the Quigley Hein plaque index\(^3\)), both overall and interproximally, after 12 and 24 weeks’ treatment

Results
- Subjects using the anhydrous test dentifrice demonstrated statistically significantly lower whole mouth gingival bleeding (mean BI) compared to those using the SMFP dentifrice, after 24 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 12, Figure 1; mean MGI, Figure 2 and mean PI, Figure 3 at 12 and 24 weeks) compared to the sodium monofluorophosphate dentifrice

Figure 1. Whole Mouth Mean Bleeding Index (BI)
Safety

One treatment emergent adverse event (TEAE) was observed in the sodium monofluorophosphate dentifrice group. This was mild in intensity and not considered to be treatment related. No serious AEs were reported.

Conclusion

The anhydrous test dentifrice containing 0.454% stannous fluoride was statistically significantly superior to sodium monofluorophosphate dentifrice in controlling gingivitis (gingival bleeding, BI and visual signs of gingival inflammation, MGI), and supra-gingival plaque, (PI). The magnitudes of the differences (BI, MGI and PI) observed between the test and control treatments in this study are considered clinically relevant.

Both treatments were well tolerated.

References:

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