A clinical study investigating the stain removal properties of two dentifrices

Nehme M et al. GSK data on file

Aim
- The aim of this study was to investigate the ability of a test dentifrice containing 0.454% stannous fluoride to remove the natural dental stain, compared to a marketed dentifrice, after 8 weeks of twice-daily use

Primary Objective:
- To compare the level of dental stain following 8 weeks of regular brushing with test dentifrice vs. control dentifrice

Secondary Objectives:
- To compare levels of dental stain after 4 weeks of regular brushing with test dentifrice vs. control dentifrice
- To evaluate changes from baseline in the level of dental stain after 4 and 8 weeks of regular brushing with test dentifrice vs. control dentifrice
- To evaluate and compare the area and the intensity of dental stain for each dentifrice after 4 and 8 weeks of regular brushing

Study products
- Test: Anhydrous dentifrice containing 0.454% stannous fluoride with the inactive ingredient 5% sodium tripolyphosphate
- Control: Marketed dentifrice containing 0.24% sodium fluoride, 0.30% Triclosan (Colgate® Total Whitening)

Methods
- Randomized, examiner-blind, two-treatment arm, parallel-design, single-site clinical trial in 126 healthy subjects, aged ≥18 years, with 16 natural teeth (including the 12 anterior teeth) and a whole mouth baseline Lobene Stain Index (LSI) score of ≥25
- At baseline, dental stain was assessed using LSI on the facial surfaces of 12 anterior teeth and lingual surfaces of 6 anterior teeth
- Eligible subjects were stratified by baseline LSI score and smoking status, then randomized to one of the 2 treatment groups. Subjects were instructed to brush twice-daily with their assigned dentifrice for the next 8 weeks
- Dental stain assessments were repeated at 4 and 8 weeks. An oral soft tissue (OST) examination was performed at every visit
Results

Efficacy

- Use of both study treatments resulted in similar decreases in dental stain over the course of the 8-week treatment period.
- Compared to the control dentifrice, the test dentifrice showed:
  - No significant differences in the reduction of dental stain at 8 weeks (primary endpoint) and 4 weeks (secondary endpoint).
- Both dentifrices significantly reduced dental stain from baseline at 4 and 8 weeks ($p<0.0001$).

Safety

- No serious adverse events reported.
- Three treatment emergent adverse events (TEAEs) were reported (two oral AEs and one non-oral AE) for two subjects (in the control dentifrice group); all were mild in intensity and were not considered to be treatment related.

Dental stain

No statistically significant differences in overall stain reduction for test dentifrice compared to control dentifrice after 4 weeks ($p=0.9557$) or 8 weeks ($p=0.1425$) of twice daily brushing. Scale ranges 0-9.

Conclusions

- The test anhydrous 0.454% stannous fluoride dentifrice showed no significant differences in dental stain reduction vs. the control dentifrice after 4 and 8 weeks of brushing. Both dentifrices significantly reduced dental stain vs. baseline after 4 and 8 weeks of brushing.