A clinical study investigating the staining potential of two dentifrices


Aim

The aim of this study was to investigate the staining potential of a test anhydrous dentifrice containing 0.454% stannous fluoride, compared to a standard marketed fluoride dentifrice, following twice-daily brushing for 8 weeks. In addition, its staining potential was compared to a marketed stannous fluoride dentifrice as a benchmark.

Primary Objective:

To compare the level of dental stain build up following 8 weeks of regular brushing

Secondary Objectives:

To compare the level of dental stain build up following 4 weeks of regular brushing
To evaluate the level of dental stain build up following 4 and 8 weeks regular brushing from baseline
To compare the area and intensity of the stain formed after 4 and 8 weeks of regular brushing

Exploratory Objective:

To evaluate and compare the level of dental stain build up from baseline, following 4 and 8 weeks of regular brushing with an experimental stannous fluoride dentifrice (test), a marketed fluoride dentifrice (control) and a marketed stannous fluoride dentifrice (comparator)

Study products

Test: Anhydrous dentifrice containing 0.454% stannous fluoride with the inactive ingredient 5% sodium tripolyphosphate
Control: Marketed dentifrice containing 0.76% sodium monofluorophosphate
Comparator: Marketed dentifrice containing 0.454% stannous fluoride with hexametaphosphate

Methods

Randomized, examiner-blind, three-arm parallel-design, single-site clinical trial in 131 healthy subjects aged 18 years and above, in good oral health, with at least 16 natural teeth (including the 12 anterior teeth, with all facial and lingual surfaces gradable for stain assessment)

At baseline, subjects were assessed for dental stain assessment using the Lobene Stain Index (LSI) on the facial and lingual surfaces of the 12 anterior teeth (termed the pre-baseline LSI score)

Eligible subjects received dental prophylaxis of the anterior teeth to remove all visible stains from their tooth surfaces so that an LSI of 0 was achieved

Subjects were then stratified by their pre-baseline LSI and smoking status, and randomized to treatment. Subjects were instructed to brush twice-daily with their study dentifrice for the next 8 weeks. Subjects were allocated to treatment (Test:Control:Comparator) in a 3:3:1 ratio

At 4 weeks and 8 weeks a dental stain assessment of the anterior teeth (facial and lingual surfaces) using the LSI was completed

An oral soft tissue examination was completed at every study visit
Results

Efficacy

- There was no significant difference ($p=0.5050$) in dental stain build up between the test dentifrice (0.454% stannous fluoride) and the control dentifrice after 8 weeks of brushing (primary endpoint).

Dental stain

Randomized subjects received prophylaxis and were assigned baseline LSI score zero.

*LSI Area x Intensity scores can range from 0-9.
†$p=0.0156$ vs test dentifrice at Week 4

- There were no statistically significant differences between the test dentifrice (0.454% stannous fluoride) and the control dentifrice for any of the secondary outcomes:
  - dental stain at 4 weeks
  - dental stain build up from baseline following 4 and 8 weeks of regular brushing
  - the area and intensity of stain formed after 4 and 8 weeks of regular brushing

- The exploratory analyses indicated that twice-daily use of the marketed comparator dentifrice (0.454% stannous fluoride) may result in more dental stain build up at 4 and 8 weeks. However, further studies would be required to understand this apparent difference further in light of the published clinical data for this marketed dentifrice.

Safety

- Eight oral adverse events (AEs) were reported, six of which were considered to be treatment related (four in the test group; two AEs in the control group). Two AEs were moderate in intensity (both in the test group); all others were mild. There were no serious AEs.

Conclusions

- There were no significant differences in stain build up between the test dentifrice (0.454% stannous fluoride) and the control dentifrice (a sodium monofluorophosphate dentifrice) after 4 and 8 weeks of twice-daily use. Study treatments were well tolerated.