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A study to investigate the effect of a sensitivity toothpaste in providing relief from tooth sensitivity

Submission date
04/04/2016

Recruitment status
No longer recruiting

Registration date
25/04/2016

Overall study status
Completed

Last Edited
07/04/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sensitive teeth (also known as dentine hypersensitivity (DH)) can be a painful condition which happens when an area of the tooth at the gum edge becomes exposed. It is thought that the short, sharp pain associated with DH is due to stimuli such hot, cold, touch, sweet and/or sour travelling down open dentine tubules (tiny channels) within the tooth and reaching the tooth's nerve and causing pain. Products used to treat the symptoms of sensitive teeth are varied and include home use products, such as toothpastes and mouth rinses or professionally applied varnishes. Toothpastes are routinely used for the treatment of sensitive teeth and some are thought to work by blocking the dentinal tubules thus reducing the ability of the pain triggering stimulus to reach the tooth's nerve and stopping the pain. Stannous fluoride has been incorporated into oral hygiene products directed at reducing tooth sensitivity since the 1960s. The long term effect of stannous fluoride containing toothpastes in reducing tooth sensitivity has been reported in a number of published studies, with some studies also reporting a short term effect. The aim of this study is to investigate the ability of an experimental stannous fluoride toothpaste in providing relief from tooth sensitivity following a single use when compared to a standard fluoride toothpaste.

Who can participate?
Adults aged 18-65 with sensitive teeth.

What does the study involve?
Al participants undergo an initial assessment to see how sensitive their teeth are. They are then randomly allocated to one of two groups. For the first visit to the study clinic, those in group 1 are given the test toothpaste containing stannous fluoride to apply directly to the gum line of two sensitive teeth using their finger, rubbing it into the gum for 1 minute. They are asked not to rinse afterwards Those in group 2 apply a "control" toothpaste not containing stannous fluoride in the same way. For the second visit, all participants are asked to brush their teeth using their assigned toothpaste (either the test or control toothpaste) for at least one minute. They are asked to rinse with tap water after brushing for no longer than 5 seconds. They are then sent home with instructions on how to brush their teeth and their assigned toothpaste.

They all brush their teeth using these instructions twice a day for the next 3 days. They then go to the study clinic a final time where assessments are made to see if there have been any changes to teeth sensitivity.

What are the possible benefits and risks of participating?
There are no direct benefits for the participants taking part in the study, but they may help the dental profession further their knowledge in the treatment of tooth sensitivity. The risks for the participants taking part in the study are minimal. They may experience tooth discomfort during the sensitivity assessments. The assessments for tooth sensitivity require applying stimuli (touch and cold air) to their teeth which may cause a short sharp pain. The stimuli are of a short duration and are no different than the discomfort that may be experienced by the participants in everyday life, for example, by brushing their teeth with cold water, or having a cold drink.

Where is the study run from?
Bristol Dental School and Hospital, Clinical Trials Unit

When is the study starting and how long is it expected to run for?
February 2016 to June 2016

Who is funding the study?
GlaxoSmithKline

Who is the main contact?
Professor Nicola West

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02751450

Protocol serial number

205084

Study information

Scientific Title
A clinical study investigating the efficacy of an occluding dentifrice in providing relief from dentinal hypersensitivity

Study objectives
To investigate the efficacy of an experimental stannous fluoride containing dentifrice in relieving dentinal hypersensitivity (DH) after short term use compared with a standard fluoride dentifrice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter, 08/02/2016, ref: 16/SW/0006

Study design
Single centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tooth sensitivity

Interventions
1. Test toothpaste: Experimental dentifrice containing 0.454% w/w stannous fluoride (1100ppm fluoride)
2. Control toothpaste: toothpaste containing 0.76% w/w sodium monofluorophosphate (1000ppm fluoride)

Supervised topical application of assigned toothpaste:
Subjects will apply (under supervision) a pea-sized dose to each of two qualifying teeth using their finger by direct application and gently rubbing into the tooth’s cervical margin (gum line) for 60 seconds. No rinsing will be permitted.

Supervised brushing with assigned toothpaste (Visit 2):
Before leaving the site (after all the clinical assessments have been completed), subjects will brush their whole mouth for at least one minute under supervision. Subjects will be permitted to rinse with 5 ml tap water (kept at room temperature) for a maximum 5 timed seconds.

At home brushing instruction with assigned toothpaste - twice daily for 3 days:

Test toothpaste:
Subjects will be instructed to dose a dry toothbrush with a full strip of toothpaste. Subjects will then brush each of the two selected sensitive test teeth first, followed by the whole mouth thoroughly for at least 1 minute. Subjects will be permitted to rinse with tap water.

Control toothpaste:
Subjects will be instructed to apply a full brush head of toothpaste to a dry toothbrush. Subjects will then brush the whole mouth thoroughly for at least 1 minute. Subjects will be permitted to rinse with tap water.

Intervention Type
Device

Primary outcome(s)
Change in teeth sensitivity, assessed using the Schiff sensitivity score measured at baseline and again at day 3

Key secondary outcome(s))
Change in threshold of tactile sensitivity, measured using a a Yeaple probe at baseline and again at day 3

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Consent: Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the informed consent form.
2. Aged 18-65 years.
3. Good general and mental health with, in the opinion of the investigator or medically qualified designee:
3.1. No clinically significant and relevant abnormalities of medical history or oral examination.
3.2. Absence of any condition that would impact on the subject’s safety or well-being or affect the individual’s ability to understand and follow study procedures and requirements.
4. Understands and is willing, able and likely to comply with all study procedures and restrictions.
5. Dental health:
At Visit 1 (Screening):
5.1. Self-reported history of dentinal hypersensitivity (DH) lasting more than six months but not more than 10 years.
5.2. Minimum of 20 natural teeth.
5.3. Minimum of 2 accessible non-adjacent teeth (incisors, canines, pre-molars), preferably in different quadrants, that meet all of the following criteria:
5.3.1. Signs of facial/cervical gingival recession and/or signs of erosion or abrasion (EAR).
5.3.2. Tooth with MGI score =0 adjacent to the test area (exposed dentine) only [Lobene, 1986] and a clinical mobility of ≤1
5.3.3. Tooth with signs of sensitivity measured by qualifying evaporative air assessment (Y/N response)
At Visit 2, Baseline (Pre-treatment):
5.4. Minimum of two, non-adjacent accessible teeth (incisors, canines, pre-molars), that meet all

of the following criteria:
5.4.1. Tooth with signs of sensitivity, measured by qualifying tactile stimulus (Yeaple ≤ 20g) and evaporative air assessment (Schiff sensitivity score ≥ 2)

Note: All teeth which meet the EAR, MGI and mobility inclusion criteria and none of the dentition exclusion criteria at Screening should be assessed by tactile stimulus at Visit 2. Those teeth which meet the required tactile threshold (Yeaple ≤ 20g) should then be assessed by evaporative air stimulus. The examiner will select two Test Teeth from those which meet both the tactile threshold and Schiff sensitivity score criteria. Test Teeth should not be adjacent to each other and preferably in different quadrants.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Women who are known to be pregnant or who are intending to become pregnant over the duration of the study
2. Women who are breast-feeding
3. Known or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients
4. Clinical study/experimental product:
4.1. Participation in another clinical study (including cosmetic studies) or receipt of an investigational drug within 30 days of the screening visit.
4.2. Previous participation in this study
5. Recent history (within the last year) of alcohol or other substance abuse
6. An employee of the sponsor or the study site or members of their immediate family
The site for this protocol is the Clinical trials Unit in the Bristol Dental School and Hospital. Employees of the Bristol Dental School and Hospital not associated with the Clinical Trials unit are eligible to participate
7. Disease
7.1. Presence of chronic debilitating disease which, in the opinion of the investigator, could affect study outcomes
7.2. Any condition which, in the opinion of the investigator, causes xerostomia
8. General dentition exclusions:
8.1. Dental prophylaxis within 4 weeks of screening.
8.2. Tongue or lip piercing or presence of dental implants.

8.3. Desensitizing treatment within 8 weeks of screening (professional sensitivity treatments and non-dentifrice sensitivity treatments).
8.4. Gross periodontal disease, treatment of periodontal disease (including surgery) within 12 months of Screening, scaling or root planning within 3 months of screening
8.5. Teeth bleaching within 8 weeks of screening
9. Specific dentition exclusions for test teeth:
9.1. Tooth with evidence of current or recent caries, or reported treatment of decay within 12 months of Screening
9.2. Tooth with exposed dentine but with deep, defective or facial restorations, teeth used as abutments for fixed or removable partial dentures, teeth with full crowns or veneers, orthodontic bands or cracked enamel. Sensitive teeth with contributing aetiologies other than erosion, abrasion or recession of exposed dentine
9.3. Sensitive tooth not expected to respond to treatment with an over-the-counter dentifrice in the opinion of the investigator
10. Product use:
10.1. Use of an oral care product indicated for the relief of dentine hypersensitivity within 8 weeks of screening (subjects will be required to bring their current oral care products to the site in order to verify the absence of known anti-sensitivity ingredients)
10.2. Use of a sensitivity toothpaste for instant relief of tooth sensitivity within two weeks of screening.
11. Concomitant medication:
11.1. Daily doses of medication/treatments which, in the opinion of the investigator, could interfere with the perception of pain. Examples of such medications include analgesics, anticonvulsants, antihistamines that cause marked or moderate sedation, sedatives, tranquilisers, anti-depressants, mood-altering and anti-inflammatory drugs
11.2. Currently taking antibiotics or has taken antibiotics within 2 weeks of Baseline
11.3. Daily dose of a medication which, in the opinion of the investigator, is causing xerostomia
12. Any subject who, in the judgment of the investigator, should not participate in the study

Date of first enrolment
17/02/2016

Date of final enrolment
27/05/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Trials Unit
Bristol Dental School and Hospital
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BS1 2LY

Sponsor information

Organisation
GlaxoSmithKline Consumer Healthcare

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2019	07/04/2020	Yes	No
Basic results				No	No
HRA research summary			28/06/2023	No	No