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Does a new toothpaste act as required to successfully treat dentine hypersensitivity?

Submission date
26/07/2016

Recruitment status
No longer recruiting

Registration date
29/07/2016

Overall study status
Completed

Last Edited
15/02/2019

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Tooth sensitivity can occur when tiny holes in the dentine of a tooth become exposed. Triggers such as cold air or touch travel down the small holes or tubules in dentine reaching the tooth nerve and causing a short sharp pain. The aim of this study is to look at the effect of an experimental toothpaste containing stannous fluoride (a toothpaste ingredient proven to be effective against tooth sensitivity) to block dentine tubules. Blocking dentine tubules is known to reduce the pain of tooth sensitivity. The ability of the stannous fluoride toothpaste to block dentine tubules will be compared to regular fluoride toothpaste and mineral water (negative control).

Who can participate?
Healthy volunteers aged between 18 and 80

What does the study involve?
Participants wear an oral appliance (like a brace) which contains samples of dentine. The samples are exposed to the mouth just as teeth are normally. There are three 10-day treatment periods. Participants receive one treatment per period. Over the course of the study each participant receives all three treatments in a random order. The treatments are stannous fluoride toothpaste, standard fluoride toothpaste, and mineral water. The dentine samples are examined after 1, 4, 8 and 10 days of treatment using scanning electron microscopy (SEM). This microscope allows us to see the small holes in dentine and determine if the toothpaste has blocked them. In addition, the strength of any dentine tubule blocking provided by the treatments is tested by exposing the dentine samples to an acid challenge (orange juice) after 9 and 10 days treatment.

What are the possible benefits and risks of participating?
There will be no direct, immediate benefit to participants from taking part in this study, however, they will have helped the dental profession gain a better understanding of products that aim to block dentine tubules and treat dentine hypersensitivity. We do not expect volunteers to experience any side effects from the toothpaste used in this study, but there is always the possibility that a rare or previously unknown side effect may occur in someone using a new toothpaste. It is also possible that a participant may be allergic to one of the ingredients within the study products. Participants will be asked to inform staff if they have any allergies or

are sensitive to any over-the-counter toothpastes, and will be given a list of ingredients to check. Dental staff are available in the event of a side effect or allergy.

Where is the study run from?
Bristol Dental Hospital and School (UK)

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

Who is funding the study?
GlaxoSmithKline Consumer Healthcare (GSKCH) (UK)

Who is the main contact?
Prof. Nicola West
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT02768194

Secondary identifying numbers
205699

Study information

Scientific Title
Assessment of dentine tubule occlusion in a modified in situ model

Study objectives
A new toothpaste designed to treat dentine hypersensitivity will occlude dentine tubules better than a standard fluoride toothpaste or negative water control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter Research Ethics Committee, 20/06/2016, REC ref: 16/SW/0123

Study design
Single-centre single-blind (with respect to the persons responsible for performing the dentine sample analysis) randomised three-treatment three-period crossover design modified in situ study in healthy volunteers

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Dentine hypersensitivity

Interventions
1. Experimental occluding (test) toothpaste containing 0.454% w/w stannous fluoride
2. Standard fluoride (control) toothpaste
3. Water (control)

There are three 10-day treatment periods. Participants will receive one treatment per period. Over the course of the study each participant will receive all three treatments, the order of the treatments for each participant will be determined according to the randomisation schedule.

During each study day participants will each wear two oral appliances one on the right and one on the left side of their buccal cavity. Each appliance will hold 4 dentine samples. Dentine

samples will be imaged by scanning electron microscopy (SEM) prior to the start of the start of the study to provide a baseline measure of tubule occlusion.

The appliances will be inserted at the study site each study day at 9:00 +/- 30 minutes. After a minimum of an hour study participants will return to the study site, remove their appliance and study staff will brush the dentine samples in each appliance ex-situ for a timed minute with the study product to which they have been randomised. Where the study product is a toothpaste, a 1:3 (w/w) slurry of toothpaste to water will be prepared on the participants arrival at the study site and the appliances immersed in this during brushing. Where the participant is randomised to water, each appliance will be brushed submerged in water. Treatments will be repeated in the same was at 14:00 +/- 30 min. Similar to treatment 1, participants will wear their appliances for a minimum of an hour before this treatment, Participants will also wear their appliances for a minimum of an hour after this treatment. Appliances will be removed for up to an hour over lunch and stored in a moist pot.

At the end of each day participants will return to the study site and return their appliance. On days 1, 4, 8 and 10 one dentine sample will be removed from each appliance and replaced with a resin blank. Removed samples will be imaged using SEM.

On days 9 and 10 of each treatment period in addition there will be two acid challenges which will occur minimum of 60 minutes after each treatment. Acid challenge with orange juice will occur in situ, participants being asked to swish a total of 250ml of orange juice around their mouths and over their appliances over a 10-minute period (25 ml/minute), expectorating after each minute. following this participants will be asked to swill their mouths for 5 seconds with 10 ml of mineral water. Following the afternoon acid challenge and swill the participants will remove their appliances.

Before the study start there will be a washout period of a minimum of 24 hours during which time participants will be asked to use a home toothpaste and manual toothbrush. Participants will also be asked to use the home toothpaste and toothbrush for the duration of the study.

Intervention Type
Other

Primary outcome measure
The primary efficacy variable will be the change from pre-dose in the mean occlusion classification score calculated from the independent classifications of three trained, blinded examiners for each SEM image. The mean will only be calculated if at least 2 examiners grade the image. Images not graded by at least 2 examiners will be considered ‘not evaluable’. The primary comparisons are between the experimental dentifrice and water at 8 days of treatment.

Secondary outcome measures
The secondary outcome measure will consist of the same treatment comparison as for the primary outcome, but will be performed for days 1, 4 and 10 using the same model.

Overall study start date
27/06/2016

Completion date
02/09/2016

Eligibility

Key inclusion criteria
1. Demonstrates understanding of the study procedures, restrictions 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 between 18 and 80 years
3. Understands and is willing, able and likely to comply with all study procedures and restrictions
4. Good general and mental health with, in the opinion of the investigator or medically qualified designee:
4.1. No clinically significant and relevant abnormalities in medical history or upon oral examination
4.2. Absence of any condition that would impact on the subject's safety or wellbeing or affect the individual's ability to understand and follow procedures and requirements
5. Able to accommodate the lower bi-lateral buccal intra-oral appliances each fitted with four dentine samples

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
28

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 breastfeeding
3. Current or recurrent disease/dental pathology that in the opinion of the investigator could affect the study outcomes
4. Current susceptibility to acid regurgitation
5. Any orthodontic appliances, restorations, bridgework or dentures that in the opinion of the investigator would interfere with the study outcomes
6. Recurrent or regular aphthous ulcers
7. Severe gingivitis, carious lesions and periodontal disease
8. Signs of severe dental erosion
9. Any condition or medication which in the opinion of the investigator is currently causing xerostomia
10. Individuals who require antibiotic prophylaxis for dental procedures
11. Known or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients
12. Participation in another study (clinical or cosmetic studies) or receipt of an investigational

drug within 15 days of the screening visit
13. Previous participation in this study
14. Recent history (within the last year) of alcohol or other substance abuse
15. 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
16. Any subject who, in the judgement of the investigator, should not participate in the study

Date of first enrolment
27/06/2016

Date of final enrolment
04/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Dental Hospital and School
Clinical Trials Unit
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Sponsor information

Organisation
GlaxoSmithKline Consumer Healthcare (GSKCH) (UK)

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Sponsor type
Industry

ROR

https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline Consumer Healthcare (GSKCH) (UK)

Results and Publications

Publication and dissemination plan
It is anticipated that the results of this study will be presented at scientific conferences and published in peer-reviewed journals

Intention to publish date
01/06/2017

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	01/09/2018	15/02/2019	Yes	No
HRA research summary			28/06/2023	No	No