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The protective effect of toothpaste against tooth erosion

Submission date
12/05/2017

Recruitment status
No longer recruiting

Registration date
22/05/2017

Overall study status
Completed

Last Edited
24/10/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
One of the effects of the growth of the food and drinks industry is the huge increase in the consumption of soft drinks, fruit juices and sport drinks. Many drink products are acidic in nature, for example, citrus fruit drinks such as orange or grapefruit juice or certain fruit squashes and fizzy drinks. Such drinks, if taken in excess, will promote erosion of the tooth surface, erosion being a loss of tooth substance by a chemical process not involving bacteria. The incidence of tooth erosion by drinks is becoming an ever-increasing problem and has led to an increased scientific awareness within the dental community. Stannous fluoride has been shown to provide some protection for the enamel against acid attack. This study will evaluate the protective effects of a toothpaste containing stannous compared to a conventional toothpaste. The aim is to compare the effectiveness of the two toothpastes to protect against enamel erosion after 10 days of use.

Who can participate?
Healthy volunteers aged 18 and over.

What does the study involve?
Participants are fitted with an appliance that fits in the roof of their mouth. The appliance is similar in design to a removable orthodontic appliance (brace). The appliance contains two human enamel samples that have been properly sterilized to meet human clinical testing standards. Participants are randomly allocated to use one of the two toothpastes across four study periods lasting 10 days each. Each participant uses each toothpaste twice during the study. Each day participants brush their teeth in the morning using an assigned non-treatment toothpaste and toothbrush (at home). At the clinical site participants collect their oral appliance to wear for about 6 hours. At the site, participants perform supervised ‘swishing’ with their assigned treatment toothpaste slurry (toothpaste swished around in their mouth) twice a day for 60 seconds. Participants also rinse their mouths with orange juice (acid challenge) four times each treatment day with their appliance in their mouth. Acid challenges are done by swishing 25 ml orange juice in their mouth for one minute, spitting it out and repeating for a total of 10 swishes in each challenge. Participants’ oral appliances are placed in a moist pot for overnight storage. On Day 10 of each treatment period the enamel samples are removed from the participant’s appliance, to assess whether the toothpastes protect against enamel loss. New

enamel samples are inserted into the appliance for each treatment period. Within two weeks of completing the last treatment period, participants attend a follow-up assessment, including a brief interview and oral examination.

What are the possible benefits and risks of participating?
There is no direct immediate benefit to the participants from taking part in this research study. However, they will have helped the dental profession gain a better understanding of products that aim to reduce and protect against enamel erosion. There are no notable risks involved with participating.

Where is the study run from?
Bristol Dental Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2017 to August 2017

Who is funding the study?
Proctor and Gamble Company (UK)

Who is the main contact?
Professor Nicola West

Contact information

Type(s)
Scientific

Contact name
Prof Nicola West

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Bristol Dental School and Hospital
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Additional identifiers

Protocol serial number
Clinical Protocol 2017015

Study information

Scientific Title

A clinical study to measure the anti-erosion properties of two dentifrices

Study objectives
The aim of this study is to compare the enamel protection efficacy (loss of tooth enamel as measured by surfometry) of two dentifrices in a 10-day in situ erosion model.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Central Bristol, 10/04/2017, ref: 17/SW/0071

Study design
Single center double-blind randomised supervised-usage two-treatment four-period crossover study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Tooth enamel erosion

Interventions
For this study, there is a screening visit, 4 treatment periods, followed by a follow-up visit within 14 days of the last treatment visit. Each treatment period consists of 10 'week days' (Monday-Friday). The participants do not attend the study site at the weekend (Saturday and Sunday). In total, the study will last approximately 10 weeks per participant.

At the screening visit, the participants are provided with a standard, commercially available toothpaste and toothbrush instead of their normal brush and paste, for the duration of the study, until the follow-up visit. They will be requested to use these products twice daily, including weekends.
The participants will be randomised at their first treatment visit following screening. They will be randomly assigned (according to a list as generated by the study statistician) to one of four treatment sequences: AABB, BBAA, ABBA, and BAAB. The letters 'A' and 'B' correspond to each of the two toothpastes being tested during the treatment phase of the study. The two treatment toothpastes are both commercially available products.
The test toothpastes will be prepared as a slurry for administration to the participants at a ratio of 3 g toothpaste:10 ml water and will be administered to the participants twice per treatment day.

During the treatment period of the study, the participants will wear an upper palatal intra-oral appliance fitted with two human enamel samples. The appliances will be positioned in the roof of the participants mouth and made specifically to fit that participant. The enamel samples will be replaced after the end of each treatment period, and new samples fitted.

On each treatment day, participants will brush their teeth at home in their usual manner using the non-treatment toothpaste and manual toothbrush as supplied at the screening visit in the

kit box provided. Participants will then attend the Clinical Trials Unit where they will collect their upper palatal intra-oral appliance fitted with two enamel samples and place it in their mouth. The participants will wear the appliance for approximately 6 hours total over the course of each study day. While wearing the appliance, participants will swish twice a day with their assigned treatment toothpaste slurry under the supervision of clinic staff for 60 seconds. The erosive challenge will occur with the appliance in the mouth. The participants will be required to sip 25mL of orange juice over a timed minute, swishing it around their mouth, then spitting out. This is repeated 10 times so that a total of 250 ml of orange juice is exposed to the enamel samples over a 10 minute period. The erosive challenge will occur a total of four times during each treatment day.

Intervention Type
Other

Primary outcome(s)
Dental erosion measured by profilometry at baseline and Day 10 of each treatment period.

Key secondary outcome(s))
No secondary outcome measures

Completion date
11/08/2017

Eligibility

Key inclusion criteria
1. Provide written informed consent to participate in the study, and receive a copy of the signed consent form
2. Agree not to participate in any other oral/dental product studies during the course of the study
3. Agree to delay any elective dentistry (including dental prophylaxis) until the study has been completed
4. Agree to refrain from the use of any non-study dentifrice or other oral hygiene products for the duration of the study
5. Agree to return for all scheduled visits and follow study procedures
6. Be at least 18 years of age
7. Agree to refrain from taking an acidic medication (pH <5.3) during the course of the study
8. Be in good general health, as determined by the Investigator/designee based on a review of the health history/update for participation in the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Have a susceptibility to acid regurgitation
2. Have recurrent or regular aphthous ulcers
3. Have dental erosion or a previous history of being susceptible to high dental erosion after drinking sports drinks or juices
4. Have excessive gingival inflammation
5. Have severe periodontal disease, as characterized by purulent exudate, generalized mobility, and/or severe recession
6. Have any pre-existing oral or medical condition that the examiner determines may place the subject at increased health risk from study participation
7. Have unremovable mouth or tongue jewelery
8. Any subject who in the opinion of the investigator (or medically qualified designee) should not participate in the study
9. Are personnel – an employee of the Sponsor, member of the study site or family relative

Date of first enrolment
10/05/2017

Date of final enrolment
16/05/2017

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
The Procter & Gamble Company

ROR
https://ror.org/04dkns738

Funder(s)

Funder type
Industry

Funder Name
The Procter & Gamble Company

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available, as if the raw data is available and then subsequently is not analyzed appropriately by qualified experts in the area, it may lead to misinterpretation of the results.

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		01/06/2019	22/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
Protocol file		09/02/2017	24/10/2022	No	No