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A study to look at the protective effect of two toothpastes against tooth erosion

Submission date	Recruitment status	[_] Prospectively registered
22/05/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/05/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/04/2020	Oral Health	

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?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
April 2016 to July 2016

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

Who is the main contact?
Prof. Nicola West

Contact information

Type(s)
Scientific

Contact name
Prof Nicola West

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015077

Study information

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

Study objectives
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, REC Ref: 15/SW/0266

Study design
Single-centre double-blind randomised supervised-usage two-treatment four-period crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Prevention

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
Enamel erosion

Interventions
1. Participants will wear a palatal appliance that is positioned in the roof of their mouth and contains 2 enamel samples
2. Participants are asked to rinse one of the study toothpastes (a slurry of 3g toothpaste:10ml water) around for 60 seconds, twice per day
3. Participants are required to rinse their mouth with orange juice (250ml over a 10 minute period) four times a day
4. Participants are provided with toothpaste and a toothbrush to use at home from screening until the end of the study and will be required to brush their teeth twice per day, in the morning and in the evening

Intervention Type
Other

Primary outcome measure
Dental erosion measured by profilometry at baseline and Day 10

Secondary outcome measures
N/A

Overall study start date
06/04/2016

Completion date
22/07/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36

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
06/04/2016

Date of final enrolment
15/04/2016

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Proctor & Gamble Technical Centres Ltd (UK)

Sponsor details
Rusham Park
Whitehall Lane
Egham
United Kingdom
TW20 9NW

Sponsor type

Industry

ROR
https://ror.org/02a8cv967

Funder(s)

Funder type
Industry

Funder Name
Proctor and Gamble Company (UK)

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 11/02/2019:
A paper has been written and submitted to the International Journal of Dental Hygiene.

Previous publication and dissemination plan:
Conference presentation and publish the study in a peer-reviewed journal

Intention to publish date

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	01/08/2019	07/04/2020	Yes	No
HRA research summary			28/06/2023	No	No