ISRCTN55245733 https://doi.org/10.1186/ISRCTN55245733

The anti-erosion effects of two different toothpastes on tooth enamel

Submission date
02/04/2015

Recruitment status
No longer recruiting

Registration date
15/04/2015

Overall study status
Completed

Last Edited
08/07/2024

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, 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 bacterial. Stannous fluoride has been shown to provide some protection for the enamel against acid attack. This study tests whether a stannous-containing toothpaste is better compared to a conventional toothpaste.

Who can participate?
Healthy adults

What does the study involve?
Participants are randomly allocated to one of two groups. Each participant receives a stannous-containing toothpaste and a conventional toothpaste twice in a random order. The participants are asked to wear a device (palatal appliance) positioned in the roof of their mouth which contains 2 enamel samples. The palatal appliances are made specifically for each person and are similar in design to those used in orthodontic treatment. On each treatment day, participants are asked to rinse one of the study toothpastes around their mouth twice a day. They are also required to rinse their mouth with orange juice 4 times a day while wearing the appliance to replicate drinking soft drinks.

What are the possible benefits and risks of participating?
There is no direct immediate benefit to those taking part in this study. However, they may have helped in the development of a toothpaste with protective properties against damage done to the teeth by acids. Participants might find wearing the palatal appliance uncomfortable to begin with, but a clinician will be on hand to adjust the appliance accordingly. There is an extremely remote risk of transmission of prions to those taking part in the study, but this risk is not considered to be any higher than compared with having normal dental treatment. This research group have run over 50 similar trials over the past 27 years and no participant has ever had a problem. It is not expected that those taking part in the study will experience any side effects from the toothpaste formulations used in this trial. Since there is always the possibility that a

rare or previously unknown side effect may occur in when somebody uses a new toothpaste, trained dental staff will be available in the Clinical Trials Unit should any negative effect occur.

Where is the study run from?
Trial study centre: Bristol Dental School and Hospital (UK)
Trial run from: University of Bristol (UK)

When is the study starting and how long is it expected to run for?
January 2015 to June 2015

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

Who is the main contact?
Prof. N West

Contact information

Type(s)
Scientific

Contact name
Dr Nicola West

Contact details
Clinical Trials Unit (Periodontology)
Bristol Dental School and Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Additional identifiers

Protocol serial number
2014119

Study information

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

Study objectives
This study will evaluate the protective effects of a stannous-containing toothpaste compared to a conventional toothpaste by comparing the enamel protection efficacy (loss of tooth enamel as measured by surfometry) of two dentifrices in a 10-day in situ erosion model. This trial will evaluate the protective effects of stannous ions on sections of human enamel that are repeatedly subjected to a citric acid drink challenge. Loss of enamel will be evaluated and compared by the use of surfometry (profilometry).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES South West - Exeter REC, 24/03/2015, ref: 15/SW/0028

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

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Enamel erosion

Interventions
Participants will wear a palatal appliance that is positioned in the roof of their mouth and contains 2 enamel samples. Participants are asked to rinse one of the study toothpastes (a slurry of 3g toothpaste:10ml water) around for 60 seconds, twice per day. Participants are required to rinse their mouth with orange juice (250ml over a 10 minute period) 4-times a day. 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(s)
Dental erosion measured by profilometry at baseline and Day 10

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/06/2015

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. 18 years and older
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. Susceptibility to acid regurgitation
2. Recurrent or regular aphthous ulcers
3. Dental erosion or a previous history of being susceptible to high dental erosion after drinking sports drinks or juices
4. Excessive gingival inflammation
5. Severe periodontal disease, as characterized by purulent exudate, generalized mobility, and /or severe recession
6. Any pre-existing oral or medical condition that the examiner determines may place the subject at increased health risk from study participation
7. Non-removable mouth or tongue jewellery
8. Any subject who in the opinion of the investigator (or medically qualified designee) should not participate in the study
9. Personnel, i.e. an employee of the Sponsor, member of the Clinical Trials Unit at the Bristol Dental School and Hospital or family relative. Employees of the Bristol Dental School and Hospital or Bristol University not associated with the Clinical Trials Unit are eligible to participate.

Date of first enrolment
08/04/2015

Date of final enrolment
20/04/2015

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
The Procter and Gamble Company

ROR
https://ror.org/02a8cv967

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble

Alternative Name(s)
Procter & Gamble, PandG, The Procter & Gamble Company, P and G, Procter & Gamble Company, P&G

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/04/2018		Yes	No
Results article	erosion protection efficacy	17/12/2018	08/07/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	09/02/2017	24/10/2022	No	No