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An exploratory study to investigate early dental erosion

Submission date
30/11/2015

Recruitment status
No longer recruiting

Registration date
03/12/2015

Overall study status
Completed

Last Edited
13/02/2018

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental erosion is the loss of hard tooth enamel caused by acid attack without the involvement of bacteria. The very early stages of erosion involve the softening and loss of some mineral content from the enamel surface, but at this stage the condition is totally reversible because in the presence of saliva enamel can re-mineralise and re-harden. The aim of this study is to find out whether fluoride toothpaste can protect the tooth enamel from acid erosion.

Who can participate?
30 healthy subjects aged 18 or over with sound tooth enamel.

What does the study involve?
Participants are randomly allocated into two groups. One group is provided with a fluoride toothpaste to brush their teeth and the second group brush their teeth with a fluoride-free toothpaste. The study is carried out over two consecutive days. Day 1 consists of a screening visit to check the participant is eligible to take part in the study, followed by a professional clean of two of the participant's front teeth as chosen by the study dentist. The participants then brush their teeth, have an impression (a rubber mould) taken of each selected tooth, and after the impression has been taken, are asked to provide a saliva sample. On the evening between Day 1 and Day 2, the participants are required to brush their teeth at home using the toothbrush and toothpaste they have been provided with. On Day 2, the participants take part in 10 procedures over the course of the day as follows: brush their teeth, drink a lemon fruit drink (dietary acid exposure), have five separate tooth impressions taken, and donate saliva on two occasions. The tooth impressions are taken after toothbrushing, dietary acid exposure, and then after a further 2, 4 and 7 hours. The enamel surface of the two selected teeth for each participant are assessed by taking an impression at different times during the study as described above. The impressions are then be looked at using a scanning electron microscope to see any changes in appearance in the enamel tooth surface before and after toothbrushing and at different time points after the dietary acid exposure.

What are the possible benefits/risks of participating?
Whilst there are no direct, immediate benefits to the participants from taking part in this study, they may have help us gain a better understanding of the effects of early erosion and re-

mineralising of tooth enamel. The risks of erosion of the participants' teeth from drinking the lemon fruit drink will be no greater than drinking a fruit drink at home.

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?
October 2015 to December 2015.

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

Who is the main contact?
Prof Nicola West

Contact information

Type(s)
Public

Contact name
Prof Nicola West

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
204739

Study information

Scientific Title
Study to investigate the initial stages of enamel erosion in vivo

Study objectives
This is an exploratory study designed to help develop a clinical model to measure the earlier stages of dietary acid mediated enamel loss. The study uses fluoride as positive control to explore the validity of this design.

1. To compare the effect of brushing with a fluoride toothpaste on inhibiting enamel dissolution following an intra-oral dietary acid exposure, compared to brushing with a non-fluoride toothpaste, as measured by analysis of dental impressions taken of the tooth surface.
2. To compare the effect of brushing with a fluoride toothpaste on promoting enamel remineralization 2, 4 and 7 hours after an intra-oral dietary acid exposure, compared to brushing with a non-fluoride toothpaste, as measured by analysis of impressions from the tooth surface.
3. To compare the effect of brushing with a fluoride toothpaste on enamel topography, as measured by analysis of dental impressions taken of the tooth surface.
4. To explore changes in salivary calcium, pH and buffering ability prior to, following and 7 hours after an intra-oral dietary acid exposure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter, 03/09/2015, REC ref: 15/SW/0208

Study design
Single-centre examiner-blind randomised two-treatment parallel-group study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Dietary acid medicated enamel loss

Interventions
The intervention for this study, is the use of either a test or dummy toothpaste prior to an erosive challenge to assess any protective effects against enamel erosion. The erosive challenge will be in the form of a lemon fruit drink which the participants will consume over 25 minutes. The test toothpaste is a marketed fluoride toothpaste and the dummy paste contains no fluoride.

For each participant, following confirmation of eligibility to participate in the study, two suitable front teeth will be selected for assessment throughout the study. Participants will be required to brush their teeth twice under supervision with their assigned toothpaste, either test or dummy, as per randomisation schedule, and once at home. They will be instructed to use a brush-head length ribbon of toothpaste and brush their teeth in their normal manner for 1 timed minute. For the supervised brushing, participants will be required to rinse the slurry formed by brushing their teeth around their mouth for a further 30 seconds. They will then be provided with 10 ml of water to rinse out their mouth with for 10 seconds.
The enamel surface of the two selected teeth will be assessed for topographical changes using a novel impression technique. Tooth impressions will be taken before the use of the toothpaste, prior to the erosive drink and at set time points following the erosive challenge. The dental impressions will be assessed and graded following SEM imaging.

Intervention Type
Other

Primary outcome measure
1. Tooth impression grading score pre-acid challenge (baseline) and immediately following acid challenge
2. Tooth impression grading score pre-acid challenge (baseline) and 2, 4 and 7 hours post acid challenge
3. Tooth impression grading score pre-acid challenge (baseline) and immediately following brushing with a fluoride toothpaste
4. Salivary calcium concentration, pH and buffering ability pre-acid challenge, following an acid challenge and 7 hours after an acid challenge

Secondary outcome measures
Not applicable as all endpoints are exploratory

Overall study start date
14/10/2015

Completion date
18/12/2015

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 at least 18 years
3. Male or female
4. General health:
4.1. Good general and mental health with, in the opinion of the investigator or medically qualified designee no clinically significant and relevant abnormalities in medical history or upon oral examination
4.2. Absence of any condition that would impact the participant’s safety or wellbeing, or affect the participant’s ability to understand and follow study procedures and requirements
5. Dental health:
5.1. In the opinion of the investigator or medically qualified designee good oral health is evident

5.2. Two anterior maxillary teeth (tooth numbers 12, 11, 21 and 22 (FDI Numbering System)), without signs of toothwear or exposed dentine, facial restorations, abutments for fixed or removable partial dentures, full crowns or veneers, orthodontic bands or cracked enamel that would interfere with the study evaluations
6. Understands and is willing, able and likely to comply with all study procedures and restrictions

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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
4.1. 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. 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 a disease or medication which in the opinion of the investigator, will impact on assessments (for example a condition which is causing xerostomia)
7.2. Any condition or medication that in the judgement of the Investigator that is causing Xerostomia
7.3. Diabetes mellitus
7.4. Susceptibility to acid regurgitation
7.5. Be susceptible to severe dental erosion from dietary origin
8. Dental:
8.1. Gross periodontal disease, treatment of periodontal disease (including surgery) within 12 months of screening, scaling or root planing within 3 months of screening
8.2. Recurrent or regular aphthous ulcers
8.3. Untreated carious lesions
8.4. Surface irregularities, discoloration due to trauma, restorations and hypo or hyperplasic areas which, in the opinion of the investigator or dental assessor, would prevent accurate impressions and grading
9. Medication:

9.1. Daily doses of a medication which, in the opinion of the investigator, could impact the assessment, for example acidic medications
9.2. Any participant who, in the opinion of the investigator or designee, should not participate in the study
10. Other conditions:
10.1. Any condition that would impact on the subject's safety or wellbeing or affect the individual's ability to understand and follow study procedures and requirements
10.2. Any participant who, in the opinion of the investigator or designee, should not participate in the study

Date of first enrolment
14/10/2015

Date of final enrolment
05/11/2015

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
GlaxoSmithKline Consumer Healthcare UK

Sponsor details
St George's Avenue
Weybridge
Surrey
Weybridge
United Kingdom
KT13 0DE

Sponsor type
Industry

ROR
https://ror.org/01xsqw823

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline Consumer Healthcare UK

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No