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Effects of different toothpastes on fluorides kinetics release to saliva in healthy adult subjects

Submission date
18/08/2014

Recruitment status
No longer recruiting

Registration date
04/11/2014

Overall study status
Completed

Last Edited
04/11/2014

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Nowadays, fluoridated toothpastes are widely used and distributed throughout the world due to their preventive action against caries. Although fluoride is considered relatively safe when its concentration is equal and/or lower than 1500 ppm, it could have side effects at higher concentrations. Therefore, according to the European and American guidelines, when the fluoride concentration value is above 1500 ppm the toothpaste is only available for purchase in pharmacies with a medical prescription. The aims of this study are to compare the rate at which the fluoride is released into saliva between three toothpastes with different concentrations and evaluate their impact on salivary flow rate and possible toxic effects of fluoride exposure. The rationale is to find out whether the toothpastes with concentrations higher than 1500 ppm induce a higher fluoride intake during and after tooth brushing, compared to toothpastes with 1500 ppm of fluoride concentration.

Who can participate?
Healthy adult volunteers aged over 18 years.

What does the study involve?
Saliva will be collected from all participants at 9 and 11.30 am in the morning. They will be asked to refrain from eating and drinking (except water) for 2 hours. They will also asked not to brush their teeth at home or at work before the study appointment. During this visit they will be randomly allocated to one of two groups: intervention or control. Participants in the intervention group will be given a toothpaste high in fluoride and those in the control group will be asked to use a fluoride toothpaste available on the market. Saliva will be collected after brushing.

What are the possible benefits and risks of participating?
There are no risks associated with these interventions for the patient during or after the study.

Where is the study run from?
The Biology and Oral Biochemistry Research Group (GIBBO) laboratory at the Dentistry College of the University of Lisbon, Portugal.

When is the study starting and how long is it expected to run for?
March 2014 to December 2014.

Who is funding the study?
University of Lisbon (Portugal).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of different toothpastes on fluorides kinetics release to saliva in healthy adult subjects: a three-arm parallel single-centre randomised controlled trial

Study objectives
Toothpastes with different fluoride content are widely used; however, when the concentration values are above 1500 ppm, it can only be sold with medical prescription due to potential toxicity. These higher concentrations (2500 and 5000 ppm) suggest an elevated risk for systemic toxicity. The rationale is to determine whether the toothpastes with concentrations higher than 1500 ppm induce a higher fluoride intake during and after tooth brushing, comparing to toothpastes with 1500 ppm of fluoride concentration.

Hypotheses:
1. There is a significant difference in fluoride concentration present in the saliva during and after tooth brushing with different toothpastes.

2. There is a significant difference in salivary secretion induced by tooth brushing with toothpastes with different concentrations.
3. There is a significant difference in the amount of toothpaste applied to the toothbrush between the different products used in this study
4. There is a significant difference in fluoride concentration retrieved from the mouthwash and from the toothbrush after brushing with different toothpastes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dentistry College of the University of Lisbon; 12/02/2014

Study design
Three-arm parallel single-centre blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Healthy adult volunteers

Interventions
Salivary secretion capacity will be assessed in all participants at baseline.

The participants will randomly be allocated to the control and intervention arms in equal numbers (22 in each arm):
1. Intervention arm: fluoride highly concentrated dentifrices such as Fluor aid 250® (Dentaid S. L., Spain) and Colgate Duraphat® (Colgate-Palmolive Unipessoal, LDA, Portugal)
2. Control arm: traditional dentifrice, sold freely, Colgate Total® (Colgate-Palmolive Unipessoal, Lda; Portugal),

Salivary secretion rate and fluoride concentration will be recorded at defined time intervals (before toothbrushing at 0 and 10 minutes; after toothbrushing at 0, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80, 90, 100, 110 and 120 minutes) to determine if the amount of fluoride would be able to induce toxic effects in the human body.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fluor aid 250, Colgate Duraphat, Colgate Total

Primary outcome(s)

Amount of fluoride present in saliva during and after toothpaste use, expressed in milligrams, as the mean ± 95% confidence interval.

Fluoride present in the toothbrush, mouthwash and in saliva after toothpaste use, expressed in parts per million will be determined using metric techniques and a fluoride selective electrode. This value will be converted into milligrams, according to each dentifrice and its fluoride concentration. Percentage values will be determined, considering the toothpaste placed on the toothbrush (expressed in grams, and calculated from the difference of weight of the toothbrush before and after toothpaste placement) as the total amount of fluoride, meaning 100% of fluoride of exposure. All the fluoride accumulated in saliva will be determined and, based on this value, calculation will be performed for each dentifrice to determine how many times a patient would have to brush his teeth per day to cause any deleterious effect, according to the reference values for acute and chronic fluoride toxicity in the literature.

Key secondary outcome(s))
1. Concentration of fluoride present in saliva before, during and after toothpaste use, expressed in parts per million, as the mean ± 95% confidence interval
2. Amount of paste placed in the toothbrush, expressed in grams, as the mean ± 95% confidence interval
3. Fluoride wasted in the toothbrush and in the mouthwash, expressed in grams, as the mean ± 95% confidence interval
4. Fluoride wasted in the toothbrush and in the mouthwash, expressed in ppm, as the mean ± 95% confidence interval
5. Fluoride present in the toothbrush, mouthwash and in saliva after toothpaste use, expressed in percentage, as the mean ± 95% confidence interval
6. Salivary flow after brushing with the dentifrices, expressed in milliliters per minute, as the mean ± 95% confidence interval

Completion date
30/12/2014

Eligibility

Key inclusion criteria
1. Above 18 years
2. An unstimulated whole saliva flow higher than 0.1 mL/min
3. Healthy volunteers, without any systemic pathologies

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Pregnant
2. Medication that induce xerostomia
3. Does not meet inclusion criteria

Date of first enrolment
19/03/2014

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Portugal

Study participating centre
Calçada dos Mestres nº3 4ºFrente
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Sponsor information

Organisation
University of Lisbon (Portugal)

ROR
https://ror.org/01c27hj86

Funder(s)

Funder type
University/education

Funder Name
University of Lisbon (Portugal) - School of Dental Medicine; GIBBO research unit

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration