ISRCTN29509071 https://doi.org/10.1186/ISRCTN29509071

Assessment of the remineralizing effect of a toothpaste promoting the formation of tooth minerals

Submission date
15/01/2020

Recruitment status
No longer recruiting

Registration date
27/01/2020

Overall study status
Completed

Last Edited
06/09/2021

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
Some people naturally have more sensitive teeth than others due to having thinner enamel. The enamel is the outer layer of the tooth that protects it. In many cases, the tooth's enamel can be worn down by:
- Using a hard toothbrush
- Grinding teeth at night
- Regularly eating or drinking acidic foods and beverages

The study compares the effect of the three toothpastes on teeth hypersensitivity relief. One toothpaste contains mineral brushite, the other toothpaste contains mineral hydroxyapatite and the third toothpaste (control) container no minerals.

Who can participate?
Patients aged 20 – 25 years, with enamel hypersensitivity.

What does the study involve?
At visit one, dental plaque will be revealed with dye solution to assess oral hygiene level. Individual instructions on oral hygiene will be given. Participants will be provided with oral hygiene tools and will receive a toothpaste in a sealed container and will not know which type of toothpaste it is.
To assess the acid resistance of enamel, a small drop of acidic solution will be applied on the tooth surface for 1 minute. Then the solution will be completely rinsed off. The surface will be stained with staining solution and the intensity of color will be measured (enamel acid resistance). Staining will be repeated daily until the enamel repair (no staining). The number of days required for enamel resistance will be fixed (rate of enamel remineralisation). Participants won't feel any discomfort during this procedure. The enamel structure will be completely restored by the end of the study.
To assess the sensitivity of enamel, air from air/water syringe will be applied perpendicular to the cervical areas of all teeth. Subjective feelings reported by the patient will be estimated according to the 4-grade scale.

Three principal visits will be with complete examination (all described tests). After each principal visit up to 5-6 daily visits for enamel remineralisation rate assessment can be required.

What are the possible benefits and risks of participating?
Tooth enamel will be restored. There are no risks.

Where is the study run from?
Institute of Dentistry, Sechenov University, Moscow, Russia

When is the study starting and how long is it expected to run for?
March 2019 to November 2019

Who is funding the study?
Supported by the "Russian Academic Exellence Project 5-100”

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
11-18

Study information

Scientific Title
Qualitative and quantitative assessment of remineralizing effect of prophylactic toothpaste promoting brushite formation: a randomized clinical trial

Study objectives
Toothpastes with brushite are equally effective to toothpastes with hydroxyapatite for enamel hypersensitivity relief.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2018, Local ethical committee of Sechenov University (Trubetskaya str, 8, Moscow, Russia, 119991; +7(495)622-97-06; iec@sechenov.ru), ref: 11-18

Study design
Interventional randomized controlled double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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 hypersensitivity

Interventions
Participants were randomly assigned to one of the study groups:
Group 1 - used toothpaste promoting the formation of brushite (test group)
Group 2 - used toothpaste with hydroxyapatite (positive control group)
Group 3 - used toothpaste without fluoride and without hydroxyapatite (negative control group)

The allocation concealment was performed by the use of containers numbered by a “third party”.

The toothpastes (in white bottles without any titles) were placed in the containers. The weight of the pastes and bottles in different groups was the same. The patient on enrolment received a sealed container with a toothpaste. Neither patients nor researchers were aware of the type of a toothpaste received by each patient.

The patients used the prescribed pastes for a month. Control examinations were carried out at 2 weeks and 4 weeks.

Intervention Type
Other

Primary outcome measure
Teeth hypersensitivity measured with Shiff index daily for 5 - 6 days

Secondary outcome measures
1. Enamel acid resistance measured using the acid staining test daily for 5 - 6 days
2. Speed of remineralization measured as the number of days until tooth recovery using the above tests

Overall study start date
01/03/2019

Completion date
01/11/2019

Eligibility

Key inclusion criteria
1. Age 20 - 25 years
2. Enamel hypersensitivity

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
18 in each group, 54 total

Total final enrolment
60

Key exclusion criteria
1. Orthodontic appliance
2. Malocclusion
3. Allergic reactions to the components of toothpastes

4. Systemic diseases
5. Pregnancy

Date of first enrolment
10/03/2019

Date of final enrolment
10/04/2019

Locations

Countries of recruitment
Russian Federation

Study participating centre
Sechenov University
Institute of Dentistry
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Sponsor information

Organisation
Sechenov University

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Sponsor type
Government

Website
http://sechenov.ru

ROR
https://ror.org/02yqqv993

Funder(s)

Funder type
Government

Funder Name
Russian Academic Exellence Project 5-100

Funder Name
Ministry of Science and Higher Education of the Russian Federation

Alternative Name(s)
МИНИСТЕРСТВО НАУКИ И ВЫСШЕГО ОБРАЗОВАНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ, Ministry of Science and Higher Education (Russia), Ministry of Science and Higher Education, Федеральная целевая программа, Ministry of Science and Higher Education, Russia, Minobrnauki of Russia

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Russian Federation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		20/01/2020	05/02/2020	No	No
Results article		01/05/2020	06/09/2021	Yes	No