

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

Submission date 15/01/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/09/2021	Condition category Oral Health	<input type="checkbox"/> 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) contains 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 Excellence Project 5-100"

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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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

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<https://ror.org/02yqqv993>

Funder(s)

Funder type

Government

Funder Name

Russian Academic Excellence 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

