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A study to assess the effect of a new toothpaste at reducing gum disease

Submission date
04/03/2021

Recruitment status
No longer recruiting

Registration date
08/03/2021

Overall study status
Completed

Last Edited
28/09/2022

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gingivitis (gum disease) represents perhaps the most common disease of the gums, with a majority of adolescents and adults affected worldwide.
The objective of this study is to assess the efficacy of a Gingivitis Treatment Toothpaste in the reduction of gingivitis over a 12-week period by using the Modified Gingival Index and the Gingival Bleeding Index. The secondary objective is to evaluate the plaque control benefit of the toothpaste.

Who can participate?
Generally healthy adults with evidence of mild to moderate gingivitis.

What does the study involve?
Participants will be randomly assigned to either the Test group (experimental NaF dentifrice with Sodium Bicarbonate and Calcium Pyrophosphate) or the Control group (marketed regular NaF dentifrice). Both groups will use a regular manual toothbrush. Participants will use their assigned products twice daily at home for the duration of the study.
Gingivitis measurements will be taken at: Baseline, Week 4, and Week 12 visits. Plaque measurements will be taken at: Baseline and Week 12 visits. The individual appointments will be scheduled for approximately the same daytime for all visits. Participants will be instructed to abstain from any oral hygiene the morning prior to all visits.

What are the possible benefits and risks of participating?
The study is designed to assess if the participants in the Test group will experience an improvement in oral health. Participants will use the study products at home in place of their regular toothbrush and toothpaste. Products will be returned at the end of the study.
The control dentifrice (toothpaste) is currently marketed. The experimental dentifrice only contains ingredients that are in use in other marketed dentifrices with similar concentration boundaries. The risk from chemical hazard is negligible, or no greater than what would have been encountered during daily life.
Also the regular manual toothbrush is currently marketed. Toothbrushes are not anticipated to cause any serious or long-term effects on oral tissue including gingival recession. This study involves the use of toothbrushes and toothpaste as part of a normal oral hygiene routine. No

behavior with incremental risk will be requested from participants. In addition, their participation will help in the development of products that aim to improve oral health. There will be no notable risks involved with participating.

Where is the study run from?
Hadassah - Hebrew University Medical Center (Israel)

When is the study starting and how long is it expected to run for?
January 2021 to September 2021

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

Who is the main contact?
Prof. Dr Avraham Zini
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Contact information

Type(s)
Scientific

Contact name
Prof Avi Zini

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2020142

Study information

Scientific Title
A clinical study to assess the efficacy of gingivitis treatment of a sodium bicarbonate and pyrophosphate dentifrice

Study objectives
The objective of this study is to assess the efficacy of a Sodium Bicarbonate/Calcium Pyrophosphate dentifrice in the reduction of gingivitis over a 12-week period by using the Modified Gingival Index and the Gingival Bleeding Index.
Gingivitis measurements (primary endpoints) and plaque measurements (secondary endpoint) are chosen as the intended purpose of this experimental dentifrice is to treat gingivitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2021, Hadassah Medical Organization Helsinki Committee (P.O.B 12272, Jerusalem 91120, Israel; Helsinki@hadassah.org.il), ref: 0161-21-HMO

Study design
Single-center randomized controlled examiner-blind two-treatment parallel study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Prevention

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
Mild to moderate gingivitis (gum disease)

Interventions
Participants are stratified at baseline on tobacco use, mean gingivitis score, number of bleeding sites, and mean plaque index. Within these strata, participants are randomly assigned to either the Test group (new NaF dentifrice with Sodium Bicarbonate) or the Control group (marketed regular NaF dentifrice). Both dentifrices will be used with a regular manual toothbrush. The randomization will be done using a computer based program.

Participants are instructed to brush their teeth twice daily (morning and evening). They are instructed to apply enough toothpaste onto the toothbrush to cover the bristles and to brush thoroughly for 1 minute and expectorate.

Participants use only the treatment products in place of normal oral hygiene products for the duration of the study (they will be allowed to continue using floss, but they will be instructed not to add/change any other oral hygiene products).

Gingivitis measurements are taken at baseline, week 4, and week 12 visits. Plaque measurements are taken at baseline visit and week 12 visits.

Intervention Type
Supplement

Primary outcome measure
Gingival inflammation and bleeding measured by Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) at baseline, week 4, and week 12

Secondary outcome measures
Dental plaque measured by Turesky Modified Quigley Hein Plaque Index (TQHPI) at baseline, and week 12

Overall study start date
23/01/2021

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Give written informed consent prior to study participation and be given a signed copy of their informed consent form;
2. Be at least 18 years of age and typically use a manual toothbrush
3. Be in good general health as determined by the investigator/designee based on a review /update of their medical history
4. Possess a minimum of 20 natural teeth with facial and lingual scorable surfaces
5. Have a Baseline whole mouth mean MGI score of at least 1.5 but not more than 2.5
6. Have established gingivitis with 10 - 70 % bleeding sites (sites with a GBI score of 1 or 2) for baseline whole mouth mean
7. Agree not to participate in any other oral care study for the duration of this study
8. Agree not to have any elective dentistry, including dental prophylaxis, until study completion and to report any non-study dentistry received at any time during the course of this study
9. Agree to refrain from using any non-study oral hygiene products for the study duration
10. Agree to return for all their scheduled visits and to follow all study procedures

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Total final enrolment
150

Key exclusion criteria
1. Any condition requiring the need for antibiotic premedication prior to dental procedures
2. Severe periodontal disease, including but not limited to, purulent exudates, generalized mobility, and/or severe recession
3. Teeth that are grossly carious, fully crowned, or extensively restored
4. Active treatment for the following conditions: periodontitis, cancer, or a seizure disorder
5. Report to be nursing or pregnant, or intend to become pregnant any time during the course of this study
6. Taking an antibiotic, anti-inflammatory, anti-coagulant medications, chlorhexidine mouth rinse or a dental prophylaxis any time within the previous 2 weeks
7. Have any of the following: orthodontic appliances, removable partial dentures, or peri/oral piercings
8. Oral/gum surgery within the previous two months
9. Excessive calculus presence that interferes with the probing examination for Gingival Bleeding Index
10. Performing any oral hygiene the morning of their Baseline study visit
11. Use of medicated lozenges, breath mints, eating, drinking, smoking or chewing gum for at least 4 hours prior to their Baseline visit (Small sips of water will be allowed up to 45 minutes prior to the visit)
12. A disease or condition that could possibly interfere with examination/procedures or with the subject's safe completion of this study

Date of first enrolment
26/04/2021

Date of final enrolment
10/05/2021

Locations

Countries of recruitment
Israel

Study participating centre
Hadassah - Hebrew University Medical Center
Department of Community Dentistry
Faculty of Dental Medicine
Jerusalem
Israel
91120

Sponsor information

Organisation
Procter & Gamble (United States)

Sponsor details
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Sponsor type
Industry

Website
http://www.pg.com/en_US/

ROR
https://ror.org/04dkns738

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble

Alternative Name(s)
Procter & Gamble, PandG, The 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

Publication and dissemination plan

Current publication and dissemination plan as of 20/09/2022:
Planned data publication in a peer-reviewed journal.

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

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because if the raw data is available but not analyzed appropriately by qualified experts in the area, it may lead to misinterpretation of the results. Study protocol, statistical analysis plan, and other additional documents are not intended to become available online.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		28/09/2022	28/09/2022	No	No