

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

<b>Submission date</b> 04/03/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/03/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/09/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

AviZ@hadassah.org.il

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Avi Zini

**Contact details**

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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 (TQHPPI) 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

8700 Mason-Montgomery Road

Mason

United States of America

45040

1 513-622-1000

timh@pg.com

## Sponsor type

Industry

## Website

[http://www.pg.com/en\\_US/](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?
<a href="#">Basic results</a>		28/09/2022	28/09/2022	No	No