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Unlocking the potential of electric toothbrushes: a 4-week clinical study investigating the efficacy in reducing plaque among children

Submission date 18/12/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/12/2024	**Overall study status** Completed	
Last Edited 11/06/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Dental caries and gingivitis are widespread problems in the pediatric population. Uncontrolled dental plaque is the primary contributor to both caries and gingivitis, forming a problematic triad cited by dental hygienists worldwide as the 3 conditions most commonly affecting pediatric patients.
Three main contributors to uncontrolled bacterial plaque are excess dietary sugar, poor oral hygiene and the host response. Sugar exacerbates the problem of plaque by preferentially supporting the accumulation of plaque-associated bacteria and sugar has also been associated with periodontal disease when consumed at high frequency. Conversely, an at-home oral hygiene regimen that reduces plaque has the power to reverse gingivitis and potentially protect against caries.
The aim of the study is to evaluate and compare the efficacy of an electric toothbrush to a regular manual brush in the reduction of dental plaque over a 4-week period in a pediatric population by using the Turesky Modified Quigley-Hein Plaque Index.

Who can participate?
General healthy children between 6-10 years old with evidence of dental plaque.

What does the study involve?
Participants will be randomly assigned to either the test group (electric toothbrush) or the control group (a regular manual toothbrush). Participants will use their assigned toothbrush with a regular toothpaste twice daily at home for the duration of the study in place of their regular toothbrush and toothpaste. The study is designed to assess if the participants in the test group experience an improvement in oral health. Plaque measurements will be taken at the baseline visit and week 4 visits.

What are the possible benefits and risks of participating?
The study is designed to compare the efficacy of an electrical toothbrush to a regular manual

toothbrush in a randomized, parallel design over a 4-week period. This study involves the use of the test products as part of the normal daily oral hygiene routine. No behavior with increased risk will be requested from participants. The electric and manual toothbrushes and the dentifrice provided in this study are currently marketed. The risk from chemical or mechanical hazards is negligible, or no greater than what would be encountered during daily life. Taking part in this study poses minimal risk to participants.

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?
November 2024 to December 2024.

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

Who is the main contact?
Prof. Avi Zini, AviZ@hadassah.org.il

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Avi Zini

Contact details
Department of Community Dentistry
Faculty of Dental Medicine
Hadassah - Hebrew University Medical Center
Jerusalem
Israel
91120
+972-50-4048388
avrahamz@savion.huji.ac.il

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Clinical Protocol 2024060

Study information

Scientific Title
A 4-week clinical study to assess an electric toothbrush in the reduction of plaque in a children population

Study objectives
The objective of the study is to evaluate and compare the efficacy of an electric toothbrush to a regular manual brush in the reduction of dental plaque over a 4-week period in a pediatric population by using the Turesky Modified Quigley-Hein Plaque Index.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 13/10/2024, Hadassah Medical Organization Helsinki Committee (P.O.B 12272, Jerusalem, 91120, Israel; +972 26777242; Helsinki@hadassah.org.il), ref: 0401-24

Study design
Single-center examiner-blind 4-week 2 treatment parallel group randomized study design

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Comparing electric toothbrush and regular manual brush in the reduction of dental plaque

Interventions
During the baseline visit, children and their parents or legal guardians will provide informed consent, undergo a medical history review, and provide demographic information. They will then undergo an oral examination and have plaque staining applied to their teeth. The participants will be randomized into treatment groups and given instructions on how to use the assigned toothbrush and toothpaste. A pre-use questionnaire will be completed, and the next visit will be scheduled. General comments and adverse events will be recorded.

At the Week 4 visit, subjects will return with their test products. Continuance criteria will be assessed, and an oral examination and plaque staining procedure will be performed. Participants and parents will complete a post-use questionnaire to provide feedback on the products.

The randomization will be done using a computer-based program which is provided by the sponsor.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Electrical toothbrush

Primary outcome(s)

Dental plaque will be measured using the Turesky Modified Quigley Hein Plaque Index at baseline and 4 weeks

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
20/02/2025

Eligibility

Key inclusion criteria
1. Come to the site with a parent or legal guardian who has given written informed consent and received a copy of their consent following the guidelines of the Institutional Review Board of Hadassah University.
2. Be 6 to 10 years old.
3. Be in good general health condition as determined by the Investigator/designee based on a review/update of their medical history for participation in the study.
4. Possess a minimum of 16 natural teeth with facial and lingual scorable surfaces.
5. Agree to delay any elective dentistry, including dental prophylaxis, and to report any non-study dentistry received for the duration of this study.
6. Have evidence of afternoon dental plaque (per investigator's discretion).
7. Agree to maintain their same regular at-home oral hygiene routine and oral care products for this study duration.
8. Agree not to participate in any other oral care study for the duration of this study.
9. Agree to return for their scheduled visits and to follow all study procedures.
10. Refrain from eating, drinking*, and chewing gum for at least 3 hours prior to this visit and agree to follow the same restriction prior to all visits. *(Exception being allowed small sips of water up until 45 minutes prior to their appointment time.)
11. Refrain from performing any other oral hygiene after their regular morning oral hygiene prior to this visit (which had to be no later than 8 am) and agree to the same restriction prior to all visits.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
10 years

Sex

All

Key exclusion criteria
1. Any disease or condition that could be expected to interfere with examination procedures or with the subject safely completing this study (including allergies to dyes or the need for premedication prior to dental procedures).
2. Any condition requiring immediate dental treatment.
3. Fixed facial or lingual orthodontic appliances.
4. Use of antibiotics within two weeks prior to study initiation.
5. Receive dental prophylaxis within one month prior to study initiation.

Date of first enrolment
05/01/2025

Date of final enrolment
16/01/2025

Locations

Countries of recruitment
Israel

Study participating centre
Department of Community Dentistry Faculty of Dental Medicine, Hadassah - Hebrew University Medical Center
Kalman Ya'akov Man Street
Jerusalem
Israel
91120

Sponsor information

Organisation
Procter & Gamble (United States)

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 and G, 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

Individual participant data (IPD) sharing plan
Not expected to be available

IPD sharing plan summary
Not expected to be made available