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A clinical study to compare the dental plaque removal of an electric versus a manual toothbrush over a 4-week period with children age 3-6 years and 7-10 years

Submission date
23/06/2021

Recruitment status
No longer recruiting

Registration date
24/06/2021

Overall study status
Completed

Last Edited
23/10/2023

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 is a common and mild form of gum disease that causes irritation, redness and swelling of the part of the gum around the base of the teeth. Various factors are involved in the extent and severity of gingivitis. Of these, dental plaque plays a prominent role. Without adequate oral hygiene, plaque can build up rapidly and cause visible inflammation within a few days.
Even with extreme plaque accumulation, thorough oral hygiene and mechanical plaque removal reduce gingivitis. Control of plaque is an essential element in effective oral hygiene programs. Oral hygiene devices are under continuous review for effectiveness and safety, as new devices or improvements of features on existing devices are developed.
The aim of this study is to compare the effectiveness of an electric toothbrush with a new brush head to a regular manual brush at reducing gingivitis and dental plaque for children over a 4-week period.

Who can participate?
General healthy children between 3-10 years old with evidence of dental plaque and gingivitis.

What does the study involve?
Participants will be randomly assigned to either the test group (electric toothbrush with a new brush head) 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. Gingivitis and plaque measurements will be taken at the first and week 12 visits.

What are the possible benefits and risks of participating?
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 toothpaste provided in this study are currently marketed. The risk from

chemical or mechanical hazards is very low, 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?
April 2021 to October 2021

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

Who is the main contact?
Prof. Avi Zini
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Clinical Protocol 2021028

Study information

Scientific Title
A 4-week clinical study to compare an electrical toothbrush with a new brush head to a manual toothbrush in the reduction of gingivitis and plaque in a pediatric population

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/06/2021, Hadassah Medical Organization Helsinki Committee (PO Box 12272, Jerusalem
91120, Israel; +972 (0)2 6777242; Helsinki@hadassah.org.il), ref: HMO-21-0317

Primary study design
Interventional

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

Study type(s)
Prevention

Health condition(s) or problem(s) studied
General healthy children between 3-10 years old with evidence of dental plaque and gingivitis

Interventions
Participants are stratified at baseline on mean gingivitis score, mean plaque index and gender within the two age groups (3-6 years and 7-10 years). Within these strata, participants are randomly assigned to either the test group (electric toothbrush with new brush head) or the control group (regular manual toothbrush).
The randomization will be done using a computer-based program which is provided by the sponsor.
Participants are instructed to use the study products according to the manufacturer instructions (electrical toothbrush) or in their customary manner (manual toothbrush) at home twice daily (morning and evening) in place of their normal oral hygiene for the duration of the study (4 weeks). Both products will be used with a regular marketed dentifrice.
Age group 3-6 years: Parents will brush the teeth of their kids.
Age group 7-10 years: Kids will brush their own teeth under supervision.

Plaque (pre-brushing) and gingivitis measurements will be taken at baseline and week 4 visits.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
1. Gingival inflammation measured by Modified Gingival Index at baseline and week 4
2. Dental plaque (pre-brushing) measured by Turesky Modified Quigley Hein Plaque Index at baseline and week 4

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

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Come to the site with a parent or legal guardian which has given written informed consent and received a copy of their consent following the guidelines of the Institutional Review Board of Hadassah University
2. Aged 3 to 10 years old
3. 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 gingivitis and 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)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
10 Years

Sex
All

Total final enrolment
105

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 pre-medication prior to dental procedures)
2. Any condition requiring immediate dental treatment
3. Fixed facial or lingual orthodontic appliances
4. Use of antibiotics within 2 weeks prior to study initiation
5. Receive dental prophylaxis within 1 month prior to study initiation

Date of first enrolment
27/06/2021

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
Israel

Study participating centre
Dental clinic Dr. Esti Davidovich
Aharon Becker 8
Mikado Center
Tel Aviv
Israel
6964316

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
Complete datasets are the property of the trial Sponsor and are considered proprietary information. The data will be held electronically in a Procter and Gamble owned archive.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/10/2023	23/10/2023	Yes	No