ISRCTN10901742 https://doi.org/10.1186/ISRCTN10901742

A clinical study to compare the dental plaque removal of an electric versus a manual toothbrush with children age 3-6 years and 7-9 years.

Submission date
27/04/2020

Recruitment status
No longer recruiting

Registration date
28/04/2020

Overall study status
Completed

Last Edited
08/06/2021

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Despite being largely preventable, dental caries remains a significant health problem among children in both developing and industrialized nations. Even in extreme plaque accumulation conditions, thorough oral hygiene and mechanical plaque removal is reported to reduce gingivitis and restore health. Control of supragingival plaque is an essential element in effective oral hygiene programs. Oral hygiene devices are under continuous review for efficacy and safety, as new devices or improvements of features on existing devices are developed.
The objective of the study is to evaluate and compare the efficacy of a kids electrical to a kids regular manual toothbrush (both will be used with a regular toothpaste) in the reduction of dental plaque in a pediatric population aged 3-9 years.

Who could participate?
General healthy children between 3-9 years old with evidence of afternoon dental plaque.

What did the study involve?
Participants will be randomly assigned to one of four treatment sequences. Every participant will use each of the two toothbrushes (either kids manual or kids electrical toothbrush) twice. At each visit (period 1 to period 4), dental plaque was measured pre- and post-brushing.
Participants will be instructed to refrain from brushing their teeth after their morning brushing prior to all afternoon visits.
All participants will be instructed to use their regular home oral hygiene products for the duration of the study in between visits.

What will be 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 replicate-use, single-brushing, randomized, four period crossover design. Participants will use each test product under supervision twice at the study site. Products will be returned at the end of the study.

The electrical and manual toothbrushes and the dentifrice provided in this study will be currently marketed. The risk from chemical or mechanical hazards was negligible, or no greater than what would have been encountered during daily life.
This study involves the use of toothbrushes with toothpaste as part of a normal oral hygiene routine. No behavior with incremental risk is requested from participants. In addition, their participation will help in the development of products that aim to improve oral health. Taking part in this study poses minimal risk to participants.

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

When was the study starting and how long was it expected to run for?
May to June 2019.

Who was 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
Prof Avi Zini

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Study information

Scientific Title
A pilot study to evaluate plaque removal efficacy by toothbrushing in two pediatric age group

Study objectives
The objective of this research is to investigate whether the use of an electric toothbrush will result in better oral health when compared to a regular manual toothbrush with children in different age groups (measured for plaque using the Turesky Modified Quigley-Hein Plaque Index [TQHPI]).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/05/2019, Hadassah Medical Organization Helsinki Committee (P.O.B 12272, Jerusalem 91120, Israel; no tel. provided; Helsinki@hadassah.org.il), ref: 0240-19-HMO

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

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

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
General healthy children between 3-9 years old with evidence of afternoon dental plaque

Interventions
Every participant will use each of the two toothbrushes (either kids manual or kids electrical toothbrush) twice. Participants will be randomly assigned to one of four treatment sequences (ABBA, BAAB, AABB, BBAA) according to a computer-generated randomization plan prepared in advance of study execution, where A and B are the two test toothbrushes. Both products will be used with a regular marketed dentifrice.
Age group 3-6 years: Parents will brush the teeth of their kids. Parents will be provided with red safety glasses which prevent them from seeing the disclosed plaque.

Age group 7-9 years: Kids will brush their teeth under supervision by themselves, unaided by a mirror.
Electrical toothbrush: Parents/participants will be instructed to brush their (kids') teeth with the assigned electrical toothbrush and the marketed dentifrice for two minutes following the manufacturer's usage instructions.
Control (manual toothbrush): Parents/participants will be instructed to brush their (kids') teeth with the manual toothbrush in their customary manner.
All participants will be instructed to use their regular home oral hygiene products for the duration of the study in between visits.
Dental plaque measurements were taken at each afternoon visit (pre- and post-brushing).

Intervention Type
Other

Primary outcome measure
At each visit (period 1 to period 4), dental plaque (pre- and post-brushing) will be measured using the Turesky Modified Quigley-Hein Plaque Index (TQHPI)

Secondary outcome measures
A new exploratory plaque index will be measured at each visit (period 1 to period 4, pre- and post-brushing) in the age group of kids 7-9 years old

Overall study start date
08/04/2019

Completion date
30/06/2019

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. Be 3 to 9 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 and agree to the same restriction prior to all visits

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
3 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
20 kids in both age groups (3-6 years and 7-9 years)

Total final enrolment
41

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 two weeks prior to study initiation
5. Receive dental prophylaxis within one month prior to study initiation

Date of first enrolment
30/05/2019

Date of final enrolment
04/06/2019

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)

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
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2020

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?
Results article		01/11/2020	08/06/2021	Yes	No