ISRCTN15360464 https://doi.org/10.1186/ISRCTN15360464

A clinical study to investigate biomarkers from fluids of the oral cavity and the benefits on plaque and gingivitis reduction when using an electrical toothbrush with an irrigator

Submission date
21/01/2019

Recruitment status
No longer recruiting

Registration date
23/01/2019

Overall study status
Completed

Last Edited
17/03/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periodontal (gum) disease is prevalent worldwide. The critical strategy is prevention through effective daily oral hygiene and early diagnosis and treatment before further progression occurs. Since oral (mouth) fluids and dental plaque samples are easy to collect in everyday dental practice and because they contain biomarkers of gingivitis (gum inflammation), these samples may provide a good basis for a specific and improved early periodontal diagnostic tool. The aim of this study is to investigate whether the use of an electric toothbrush and an irrigator over a period of 8 weeks is able to reduce gingivitis and plaque and improve oral fluid/pathogen biomarker levels reflecting better gingival health.

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

What did the study involve?
Participants are randomly allocated to either the test group (electric toothbrush and irrigator) or the control group (regular manual toothbrush). Participants use their assigned products with a regular toothpaste twice daily at home for the duration of the study. At the beginning of the study and at weeks 2, 4, and 8 dental plaque and gingivitis status are evaluated by a dentist. Also saliva and fluids from the gingival pockets are collected for biomarker analysis. Additionally, home saliva samples are collected by the participants before all clinical visits for analysis.

What were the possible benefits and risks of participating?
The study was designed to assess if the participants in the test group experience an improvement in oral health. The participants received information by dental professionals about their oral health status and weaknesses in their oral hygiene routine. In addition, their participation helped in the development of products that aim to improve oral health. Both groups received a dental prophylaxis (cleaning procedure) at their final visit. There were no notable risks involved with participating.

Where was the study run from?
University of Bern (Switzerland)

When was the study starting and how long was it expected to run for?
November 2010 to July 2013

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

Who is the main contact?
Dr Christoph Ramseier

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Clinical Protocol 2010009

Study information

Scientific Title
Clinical parameters and oral fluid biomarkers in gingivitis subjects using a powered toothbrush with irrigator or a manual toothbrush alone: an 8-week randomized controlled clinical trial

Study objectives
The objective of the research is to investigate whether 8 weeks use of an improved homecare oral hygiene regimen that includes combination of an electric toothbrush and an irrigator will result in better gingival health (measurement of gingival index (GI) by Löe & Sillness (1963)) compared to a standard homecare oral hygiene regimen.

This study will secondarily evaluate the ability to distinguish the levels of gingivitis-associated oral fluid biomarkers and dental plaque between the two treatment groups.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Kantonale Ethikkommission Bern, Postfach 56, Murtenstrasse 31, 3010 Bern, Switzerland, Tel: 0041 31 632 86 33, Email: pfiffner@kek-unibe.ch, 08/10/2012, IRB Approval #: KEK 066/11

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

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Oral mild to moderate gingivitis

Interventions
Participants were stratified at baseline on age, tobacco use, number of bleeding sites, and mean plaque index. Within these strata, participants were randomly assigned to either the Test group (electrical toothbrush/irrigator and a standard anti-cavity toothpaste) or the Control group (regular manual toothbrush and a standard anti-cavity toothpaste).

Participants were instructed to use the study products at home twice daily (morning and evening) in place of their normal oral hygiene for the duration of the study (8 weeks). Participants were asked to refrain from flossing for the duration of the study.

Participants of the Test group were instructed to brush their teeth using the toothpaste and electrical brush according to manufacturer instructions. They were instructed to rinse their mouth with water after brushing to remove excess paste. Then Participants should rinse their mouth with the irrigator with 300 ml water for approximately 1 minute.

Participants of the Control group were instructed to brush their teeth as they normally do using the products provided. Participants were instructed to rinse their mouth with water after brushing to remove excess paste.

At baseline and at week 2, 4, and 8 plaque and gingivitis were evaluated and gingival crevicular fluid (GCF) and whole saliva (WS) were collected for biomarker analysis. Additionally, home saliva samples were collected by the participants prior to all clinical visits for metabonomics and biomarker analysis on 5 consecutive days (one sample per day).

Intervention Type
Other

Primary outcome(s)
Gingival inflammation and bleeding measured by Gingival Index (Löe & Sillness 1963) at baseline, week 2, 4, and 8

Key secondary outcome(s))

Measured at baseline, week 2, 4, and 8:
1. Gingivitis-associated oral fluid biomarkers: whole Saliva and GCF (both collected at the clinic) were quantitatively analyzed for the amount of matrix-metalloproteinase (MMP)-8 and interleukin (IL)-1β by means of ELISA technique
2. Dental plaque measured by Plaque Index (Silness-Löe 1964)

Completion date
10/07/2013

Eligibility

Key inclusion criteria
1. Be at least 18 years of age
2. Provide written informed consent prior to participation and be given a signed copy of the informed consent form
3. Be in good general health as determined by the Investigator/designee based on a review of the medical history/update for participation in the study
4. Agree to return for the scheduled clinical visits and follow study instructions
5. Agree not to participate in any other oral care study for the duration of this study
6. Agree not to use any non-study oral hygiene products for the duration of the study (including dental floss)
7. Agree to delay any elective dentistry, including dental prophylaxis (outside of the study protocol), until study completion
8. Agree to refrain from brushing their teeth and from performing any other oral hygiene procedures 12 hours prior to each visit
9. Agree to refrain from eating, chewing gum, drinking or using tobacco for 4 hours prior to each visit
10. Have at least 20 gradable teeth
11. Have at least 15 gingival bleeding sites (as described in section 13 - Löe & Silness GI)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
60

Key exclusion criteria

1. Severe periodontal disease, as characterized by purulent exudate, generalized mobility, and /or severe recession
2. Active treatment for periodontitis
3. Fixed facial or lingual orthodontic appliances
4. Regular use of electric toothbrush
5. Need of antibiotic prophylaxis prior to the dental visit
6. Antibiotic use or prescription mouth rinse use within one month prior of Screening (Visit 1)
7. Dental prophylaxis within one month prior of Screening (Visit 1)
8. Any disease or condition that could be expected to interfere with the subject safely completing the study
9. Pregnancy or lactation

Date of first enrolment
11/02/2013

Date of final enrolment
10/05/2013

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Bern, Department of Periodontology, School of Dental Medicine
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Sponsor information

Organisation
Procter and Gamble Company

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
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.

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		07/01/2021	17/03/2022	Yes	No