ISRCTN12394494 https://doi.org/10.1186/ISRCTN12394494

A new tooth brushing approach supported by an innovative hybrid toothbrush: Compared reduction of dental plaque after a single use versus an oscillating-rotating powered toothbrush

Submission date
05/02/2018

Recruitment status
No longer recruiting

Registration date
20/02/2018

Overall study status
Completed

Last Edited
08/10/2019

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims:
Oral health is one of the major concerns of dental health care professionals. In Western industrialized countries, the toothbrush is widely accepted as a simple, affordable and effective device to mechanically remove dental plaque in a shorter time. However, a wide diversity in brushing methods does exist depending on the position and motion of the brush. The aim of this study was to evaluate and compare the clinical efficacy of the first hybrid toothbrush (INAVA Hybrid) using combined mode (manual gesture associated to sonic vibrations) to a marketed oscillating-rotating powered toothbrush (Oral-B Vitality) in the reduction of dental plaque after a single use.

Who can participate?
Adult subjects presenting a deposit of dental plaque covering up to 1/3 of the cervical and a mild inflammation of gingival marginal or papillary.

What does the study involve?
On the day of the study, the subjects come to the laboratory after refraining from all oral hygiene procedures for 24 hours and without eating, drinking and smoking for the last four hours before the visit. The dentist performs a clinical examination of the state of the oral cavity, with a ”Silness and Löe Plaque Index” (PI) score and “Modified Gingival Index“ (MGI) score. After randomization, each participant receives instructions on how to use the assigned toothbrush device. The same toothpaste is provided to all the subjects. A single brushing with the studied product (hybrid toothbrush) or the comparative product (oscillating-rotating device) is performed for exactly two minutes under supervision to ensure compliance with the manufacturer’s usage instructions. Immediately after brushing, another clinical examination of

the state of the oral cavity is performed by the dentist and another PI scoring is done. The participants complete a self-assessment questionnaire of the products' acceptability after the first use.

What are the possible benefits and risks of participating?
There are no known benefits with participating in this study. The possible risk is bleeding of the gingiva.

Where is the study run from?
Demscan Poland (Gdansk- Poland)

When is the study starting and how long is it expected to run for?
September 2015 to November 2015

Who is funding the study?
Pierre Fabre Oral Care (France)

Who is the main contact?
Dr JP Gatignol (Public)
jean.philippe.gatignol@pierre-fabre.com

Contact information

Type(s)
Scientific

Contact name
Dr Jean-Philippe Gatignol

Contact details
Institut de Recherche Pierre Fabre
17 Avenue Jean Moulin
Castres
France
81106

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15E0508

Study information

Scientific Title

Oral and dental efficacy and tolerance of an electric toothbrush versus a comparative electric toothbrush marketed - use test under dental control of the reduction of dental plaque after a single use

Study objectives
The new hybrid toothbrush combining manual gesture associated to sonic vibrations is as efficient as a marketed oscillating-rotating powered toothbrush in the reduction of dental plaque.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not required: the study takes place in Poland. In that country, an electric toothbrush is considered to be a domestic electric apparatus. Conducting a clinical study with such devices does not require any approval by an ethics committee. However, the study is conducted in compliance with Good Clinical Practices and in accordance with the “Declaration of Helsinki.” Written informed consents for participation in the clinical study is obtained for all participants.

Study design
Randomized examiner-blind single-center study parallel group.

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Oral health

Interventions
On the day of the study, participants come to the laboratory after refraining from all oral hygiene procedures for 24 hours and without eating, drinking and smoking for the last four hours before the visit. The dentist performs a clinical examination of the state of the oral cavity. Participants with a ”Silness and Löe Plaque Index” (PI) score between 1.0 and 2.0 and “Modified Gingival Index“ (MGI) score between 1.0 and 2.0 are included in the study. A randomisation list for toothbrush allocation is generated using the sub routine PROC PLAN of the statistical software SAS 9.4. After randomisation, each participant receives instructions on how to use the assigned toothbrush device. The same toothpaste (Elgydium, Pierre Fabre Oral Care, France) is provided to all the subjects. A single brushing with the studied toothbrush (INAVA Hybrid -

Pierre Fabre Oral Care, France) or the comparative toothbrush (Oral-B Vitality 2D Sensitive Clean - Procter & Gamble, USA) are performed for exactly two minutes under supervision to ensure compliance with the manufacturer's usage instructions. Immediately after brushing, another clinical examination of the state of the oral cavity is performed by the dentist and another PI scoring is done. Possible adverse reactions are noted. For this post-brushing evaluation, the dentist is blinded as to the device used. The participants complete a self-assessment questionnaire of the products' acceptability after the first use.

Intervention Type
Device

Primary outcome measure
Anti-plaque efficacy of the studied toothbrush versus a comparative toothbrush is measured using the "Silness and Loe Plaque Index" immediately after usage.

Secondary outcome measures
1. Tolerance of study products is measured using clinical examinations of the oral cavity (teeth, gums, mucous membranes) for physical and functionals signs before and immediately after toothbrush use
2. Cosmetic acceptability is measured using a questionnaire filled in by the patients immediately after toothbrush use

Overall study start date
13/08/2015

Completion date
28/01/2016

Eligibility

Key inclusion criteria
1. Patients aged between 18 to 70 years old
2. Presenting at least 20 natural teeth, without implants, prosthesis or dental braces on the studied teeth
3. Presenting a "Silness and Löe Plaque Index" between 1.0 and 2.0 and a "Modified Gingival Index" between 1.0 and 2.0. at the time of inclusion
4. Not using preventive dental medications, antibiotics and/or steroids during one week before the beginning of the study
5. Never used an electric toothbrush

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
66 patients (33 per group)

Total final enrolment
66

Key exclusion criteria
1. Pregnant or nursing women or not willing to take precautions during the study
2. Subject having an uncompromised manual dexterity
3. Subject having a disease liable to interfere with study data according to the investigator
4. Subject having a cutaneous-mucosal disease liable to interfere with study data according to the investigator, especially: herpes or medical history herpes, aphtosis and medical history of aphtosis, lichen planus, chronic lupus erythematosus
5. Subject having undergone surgery, chemical or physical treatment to the concerned area in the last 3 months
6. Subject having a background of intolerance or allergy to cosmetics, to drugs or to other substances (fruits, lactose intolerant, nuts, etc.) that makes the subject ineligible or places him /her at undue risk or that forbids him/her not to eat and drink 4 hours before the study
7. Subject planning to have any dental care during the study
8. Subject having applied any topical or local product (dental gel, mouthwash, etc.) the day of the inclusion visit on the study area

Date of first enrolment
20/08/2015

Date of final enrolment
27/11/2015

Locations

Countries of recruitment
Poland

Study participating centre
Dermscan Poland
ul. Kruczkowskiego 12
Gdansk
Poland
80-288

Sponsor information

Organisation

Pierre Fabre Dermocosmetique

Sponsor details
Pierre Fabre Medicament
Hôtel Dieu
2 Rue Viguerie
Toulouse
France
31025

Sponsor type
Industry

ROR
https://ror.org/04hdhz511

Funder(s)

Funder type
Industry

Funder Name
Pierre Fabre Medicament

Results and Publications

Publication and dissemination plan
Planned publication in BMC Oral Health.

Intention to publish date
15/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr JP Gatignol (jean.philippe.gatignol@pierre-fabre.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/11/2018	08/10/2019	Yes	No