Brush head configuration - Safety and Efficacy

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23576

Source
NTR

Brief title
Brush head configuration - Safety and Efficacy

Health condition

Dental Plaque

Sponsors and support

Primary sponsor: Proctor & Gamble
Frankfurter Straße 145
61476 Kronberg im Taunus
Germany
Source(s) of monetary or material Support: Proctor & Gamble
Frankfurter Straße 145
61476 Kronberg im Taunus
Germany

Intervention

Outcome measures

Primary outcome

- Turesky Modification of the Quigley Hein Plaque Index (TQPHI)

Dental Plaque and debris will be graded using the same scale as the Turesky Index, but at the following six (6) sites:

Mesial, distal and mid surfaces on the facial aspect; Mesial, distal and mid surfaces on the lingual aspect.

The area to be graded on the mesial and distal will be determined by three reference points. These points are the line angle of the tooth to the contact point both bordered by the gingival margin. This allows a small triangular area to be graded. In the event that there is no contact between teeth, the height of contour of the tooth should be used as the reference point.

SCORE CRITERIA:

0 = No plaque / debris.

1 = Separate flecks of plaque at the cervical margin of the tooth

2 = A thin continuous band of plaque (up to 1mm) at the cervical margin of the tooth

3 = A band of plaque wider than 1mm but covering less than 1/3 of the crown of the tooth.

4 = Plaque covering at least 1/3 but less than 2/3 of the crown of the tooth

5 = Plaque covering 2/3 or more of the crown of the tooth

Secondary outcome

GINGIVAL ABRASION

A complete oral soft tissue examination will be performed at each visit prior to any test procedures. Gingival abrasions will be assessed. Before each assessment gingival abrasions will be stained by applying a disclosing solution (Mira-2-Ton®, Hager and Werken, GmbH & Co., Duisburg, Germany) using cotton swabs. The number and site location of the gingival abrasions are then recorded on CRF, with the exclusion of the third molar and central incisors regions. The gingival tissues are divided into three areas: cervical (cervical free gingiva), interdental (papillary free gingiva) and mid-gingival (attached gingiva). In the upper jaw the palatal mid-gingival area comprises the whole hard palate. The abrasions will be measured by using a PQ-William’s periodontal probe placed across the long axis of the lesions. The abrasions will be scored as "small" if =2 mm, as medium if ≥ 3 but ≤ 5 mm, and as large if >5 mm. Those lesions measuring between 2 mm and 3 mm will be assigned a score of small or medium according to nearest mm mark on the probe.

Study description

Background summary

The aim of the present study was to evaluate the effect of 3 new developed brush heads compared to a EB17 brush head in relation to gingival abrasion and plaque removing efficacy

Study objective

The 3 new developed prototype electric brush heads (A,B,C) remove 15% more plaque compared to a EB17 brush head

Study design

- Appointment 1: screening for inclusion, give written consent, instruction not to brush teeth for 48 hours.

- Appointment 2: Measurements and brushing with all 4 brush heads will be used by each subject, one brush per quadrant.

Intervention

- Removing plaque with the 4 different brushheads of an electric toothbrush

- To evaluate the efficacy of new brushheads an investigation will be carried out using a randomized single used cross-over model whereby all brushes will be used by each subject, one brush per quadrant.

- Different brushheads:

1: Prototype EB-A

2: Prototype EB-B

3: Prototype EB-C

4: EB17

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion:

1. Be between the ages of 18 and 70

2. Be in good general health as determined by the investigator/designee based on a review of the medical history/update,

3. Possess at least 5 evaluable teeth in each quadrant in the lower jaw

4. No periodontal pockets of 5mm or more

Exclusion criteria

Exclusion:

1. Orthodontic banding or wires or partial dentures,

2. Severe periodontal disease (no sites with PPD > 5mm), including but not limited to

purulent exudate, generalized mobility, and or severe recession,

3. Any disease or conditions that could be expected to interfere with examination procedures or the subject safely completing the trial.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2008
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	04-09-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1373
NTR-old	NTR1431
Other	: MEC 08/173
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results