ISRCTN38199132 https://doi.org/10.1186/ISRCTN38199132

Breath freshening effects of mechanical removal of tongue biofilm

Submission date
14/12/2015

Recruitment status
No longer recruiting

Registration date
27/01/2016

Overall study status
Completed

Last Edited
15/02/2016

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Bad breath (halitosis) is a common problem that can affect anyone at any age. Although not life threatening, it can cause distress and affect how they interact with other people. Bad breath might be caused by microbes on the surface of the tongue. Cleaning the tongue with a toothbrush has shown to reduce bad breath, but the effects are short lived and doesn't work for the whole day. The use of a newly designed tongue brush head made from soft silicone microbristles might be more successful at reducing bad breath and therefore relieve the stress and discomfort that this condition can cause. It is used on a power toothbrush handle, as sonic motions clean the tongue better than manual movements. It is also used with a tongue spray that contains mint fresh flavors and other compounds that trap smell gases. This study is looking at whether this new toothbrush combined with an antibacterial tongue spray (BreathRX tongue spray) results in long lasting fresh breath.

Who can participate?
Adults aged between 18-70 with bad breath.

What does the study involve?
Participants are randomly allocated to one of four groups. The first group is given the tongue brush to use along with the BreathRX spray, for one morning. Group 2 are given the tongue brush to use and a water spray. Participants in the third group are given BreathRX alone to use. Participants in group 4 are only given water. Bad breath is then measured for every participants in the study, for up to 6 hours. Bacteria from a tongue scrape sample is also counted to see if the root cause of bad breath –bacteria living in the dorsum (surface) of the tongue- are reduced. All participants are given all 4 treatments in turn, with a week passing before they are given the next one (this is called a washout period).

What are the possible benefits and risks of participating?
The only direct benefit for participants in this study is a possible reduction in their halitosis. However,
the information and knowledge that is gained through this study will help benefit people in the

future by selecting the best treatments. No major side effects of the treatments are expected to occur. Some participant may experience gagging or a slight burning sensation of the tongue after using the BreathRX tongue spray, but these symptoms will only last for a few seconds.

Where is the study run from?
University of the West of England (UK)

When is the study starting and how long is it expected to run for?
June 2015 to July 2015

Who is funding the study?
Philips Electronics UK

Who is the main contact?
1. Dr Saliha Saad (scientific)
2. Dr Paola Gomez-Pereira (public)

Contact information

Type(s)
Scientific

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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Philips ICBE number: ICBE-2-1652. East of England Cambridge Central NRES committee (REC reference: 14/EE/0206)

Study information

Scientific Title
Clinical study on the breath freshening effects of mechanical removal of tongue biofilm used with oral formulations

Study objectives
The primary hypothesis of this clinical investigation is that the combination of the tongue brush with the antibacterial BreathRX tongue spray delivers a long lasting fresh breath.
We hypothesized that the tongue brush with BreathRX will show a significantly higher reduction in organoleptic score at 6hrs than all other alternative treatments (tongue brush with sterile water, BreathRX alone, sterile water alone (control)).

These hypotheses will be accepted or rejected based on the outcome of this clinical investigation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hampstead NRES Committee London, 08/04/2015, ref: 15/LO/0659

Study design
Randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Halitosis

Interventions
This study is a randomized cross over investigation on a population of participants with above noticeable levels of oral malodour. Participants used four interventions once, with one week washout in between them. After each intervention, endpoints were measured 1hr, 3hr and 6hrs after treatment.

The interventions are:
1. Tongue brush with BreathRx antibacterial spray.
2. Tongue brush with water spray
3. BreathRx alone
4. Water

The tongue brush consists of 200 microbristles mounted on an EasyClean Philips Sonicare power toothbrush handle. It was used for a total of 60 sec, in 20 sec intervals. At each interval, 3 sprays of either BRx or water (approximately 0.6 mL) were placed on the tongue, followed by brushing. BRx or water alone treatments consisted of the same number and repetitions and volumes of the given spray alone.

The third arm consisted of using Breath RX on its one on the form of a spray (without the tongue brush). Participants were advised to use one spray of Breath RX and hold it for 20 seconds on the tongue before spitting it out. This was repeated a second and third time so that 3 sprays of breath RX were used in total.

The fourth arm consisted of using sterile water on its one on the form of a spray (without the tongue brush). Participants were advised to use one spray of water and hold it for 20 seconds on the tongue before spitting it out. This was repeated a second and third time so that 3 sprays of water were used in total.

Intervention Type
Device

Primary outcome measure
Assessment of oral malodor by organoleptic scoring. A trained clinician sniffed the air exhaled from the mouth and nose and subjectively confirmed or deny the presence of malodour. It scored breath odor levels using the 0–5 organoleptic scale: 0 = no odor, 1 = barely noticeable, 2 = slight odor, 3 = moderate odor, 4 = strong odor, 5 = very strong odor.

Measured 1hr, 3hr and 6hrs after treatment.

Secondary outcome measures
Measurement of the bacterial density on the tongue, as one of the main causes of oral malodor is the bacterial that inhabit the tongue dorsum. Tongue scrape samples were taken using a sterile soft toothbrush and the sample plated on fastidious anaerobe agar supplemented with 7% defibrinated horse blood for isolation of anaerobes, and supplemented with vancomycin for isolation of strict gram-negative anaerobes. Colonies were counted and tongue bacterial density calculated.

Measured 1hr, 3hr and 6hrs after treatment.

Overall study start date
02/06/2015

Completion date
11/07/2015

Eligibility

Key inclusion criteria
1. Voluntary participation in the study as documented on a subject informed consent form.
2. Availability at the investigational site at the specified study intervals and sampling times
3. Male and female between 18 and 70 years of age
4. Classified as healthy
5. Organoleptic score > 2
6. At least 20 own teeth with average oral hygiene (tooth brushing at least twice a day)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Medical history of infectious diseases
2. Severe caries, gingivitis or periodontitis
3. Antibiotic medication within 1 month prior to the start of the trial or during the trial period
4. Consumption of medicated sweets containing antimicrobial agents
5. Subjects with diabetes mellitus, bronchitis, tonsillitis, sinusitis or other conditions that may contribute to oral malodour

Date of first enrolment
02/06/2015

Date of final enrolment
13/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of the West of England
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Sponsor information

Organisation
Philips Electronics UK

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Sponsor type
Industry

ROR
https://ror.org/04ktqp584

Funder(s)

Funder type
Industry

Funder Name
Philips Electronics UK

Results and Publications

Publication and dissemination plan

Results of this clinical investigation will be published in a peer reviewed journal, and in conferences.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

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	results	12/02/2016		Yes	No
HRA research summary			26/07/2023	No	No