

Breath freshening effects of mechanical removal of tongue biofilm

Submission date 14/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/02/2016	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English Summary

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

Contact name

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Type(s)

Public

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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 hypothesis

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

Condition

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 own 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 own 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

Overall study end date

11/07/2015

Eligibility

Participant 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

Participant 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

Recruitment start date

02/06/2015

Recruitment end date

13/06/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of the West of England

Coldharbour Lane

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Sponsor information

Organisation

Philips Electronics UK

Sponsor details

Philips Centre

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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