ISRCTN67671859 https://doi.org/10.1186/ISRCTN67671859

Assessment of oral malodour and tonsil bacteria after gargling of throat with an antiseptic

Submission date 12/08/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/08/2015	**Overall study status** Completed	
Last Edited 19/08/2015	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
Other than the mouth, the ear, nose and throat (ENT) region is one of the areas most affected by bad breath, also known as halitosis or oral malodour. It is thought that one of the main causes of bad breath is an infection in the tonsils on either side of the back of the throat. However, the link between healthy tonsils to halitosis is not well studied. It is thought that the bacteria which are always present on the tonsils, even if there is no infection, produce volatile sulphur compounds (VSCs), which lead to bad breath. The aim of this study is to find out whether people with healthy tonsils can still suffer from halitosis, and if gargling with an antibacterial mouthwash can make a difference.

Who can participate?
Patients who think they have bad breath, and who have not been on antibiotics or seen an ENT doctor for sinus or tonsil problems within the past 3 months.

What does the study involve?
Participants are randomly divided into three groups. The first group gargles a benzethonium chloride mouthwash four times a day for nine days. The section group gargles an inactive (placebo) mouthwash containing sterile distilled water containing the same artificial colorants as in the active mouthwash four times a day for nine days. The third group are instructed not to gargle anything for the nine days of the study. Before the study begins and after it is finished, the levels of the VSC's in the mouth are measured. Patients are also asked how strong they think their bad breath is. During the nine days of the study, all participants have their teeth professionally cleaned by a dentist every three days.

What are the possible benefits and risks of participating?
Possible benefits for participants include possible improvement in bad breath. Risks associated with participation include allergy for antiseptic and spending time to visit hospital for PMTC.

Where is the study run from?
Division of Periodontal Health Promotion, Aichi Gakuin University Dental Hospital (Japan)

When is the study starting and how long is it expected to run for?
July 2010 to March 2016

Who is funding the study?
The Ministry of Education, Culture, Sports, Science and Technology (Japan)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessment of oral malodour and tonsillar microbiota after gargling in orophrynx with benzethonium chloride

Study objectives
1. The microbiota of healthy tonsil is one of the source of halitosis.
2. Management of the microbiota by gargling with antiseptics reduces halitosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of Aichi Gakuin University, 23/07/2010, ref: 227; and 14/03/2014, ref: 371.

Study design
Single-centre randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Halitosis without periodontitis and otolaryngological disease.

Interventions
Participants are randomly allocated into three groups:
1. Test Group: Instructed to gargle with mouthwash containing 0.004% benzethonium chloride and artificial colorants (tartrazine and Brilliant Blue FCF) for 1 minute, four times per day for 9 days.
2. Placebo Group: Instructed to gargle with the placebo mouthwash (sterile distilled water containing the artificial colorants) for 1 minute, four times per day for 9 days.
3. Control Group: Instructed not to gargle during test period.
During the 9-day test period, all of the participants underwent professional mechanical tooth

cleaning (PMTC) every 3 days. The volatile sulfur compounds (VSCs) concentration in mouth air, organoleptic score and profile of tonsillar microbiota of halitosis patient were assessed before and after gargling with benzethonium chloride.

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
Benzethonium chloride

Primary outcome measure
Comparing the concentrations of VSC's (H2S, CH3SH, and CH3SCH3) in mouth air, measured using OralChroma, and organoleptic score, determined using the Rosenberg’s scale. Outcomes are measured at baseline and after 9 days.

Secondary outcome measures
Outcomes are measured at baseline and after 9 days:
1. Concentrations of VSCs are measured using OralChroma.
2. Organoleptic assessment is judged on a 0–5 scale (Rosenberg’s scale).
3. Tongue coating score is recorded with Kojima’s scale.
4. Bacterial profiles are assessed by T-RFLP analysis.

Overall study start date
24/07/2010

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. To have visited the Aichi Gakuin University Dental Hospital and claiming oral malodour
2. No history of antibiotic use within the past 3 months
3. No history of otolaryngology consultation due to sinusitis, tonsillitis and tonsilloliths within the past 3 months

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
150

Key exclusion criteria

1) Otolaryngological disease at baseline
2) Periodontitis
3) To have used a gargle on the day of screening
4) A negative result for an organoleptic assessment (score 0)
5) Less than 26 ppb CH3SH in mouth air
6) Score of more than 30% on the Plaque Control Record

Date of first enrolment
01/08/2010

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Japan

Study participating centre
Aichi Gakuin University Dental Hospital
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Organisation
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Sponsor type
University/education

ROR
https://ror.org/01rwx7470

Funder(s)

Funder type
Government

Funder Name
The Ministry of Education, Culture, Sports, Science and Technology (JAPAN)

Results and Publications

Publication and dissemination plan
A pilot data is planned to publish in an international journal of dental field. Further plans to be confirmed at a later date.

Intention to publish date
31/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration