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Efficacy of 0.1% chlorine dioxide mouthwash in reducing oral malodour

Submission date	Recruitment status	[_] Prospectively registered
25/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/03/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/07/2020	Oral Health	

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the effects of a mouthwash containing 0.1% ClO2 used for 2 weeks on oral malodour (bad breath), periodontal (gum) status, salivary pH and flow rate, tongue coating, and bacteria in saliva.

Who can participate?
First- to third-year students at the University of Medicine and Pharmacy, Ho Chi Minh City with oral malodour

What does the study involve?
Participants are randomly allocated into two groups. In the first stage, one group is instructed to rinse with the experimental mouthwash, while the other group is instructed to rinse with the control mouthwash for 2 weeks. After 4 weeks of washing out, in the second stage, each group uses the other mouthwash for 2 weeks. Oral malodour, periodontal status, tongue coating, salivary pH and flow rate, and salivary bacteria are evaluated at the start of the study and after 2 weeks of mouthwash use.

What are the possible benefits and risks of participating?
Patients receive all treatments free of charge. No risks are expected.

Where is the study run from?
University of Medicine and Pharmacy, Ho Chi Minh City (Viet Nam)

When is the study starting and how long is it expected to run for?
February 2017 to April 2017

Who is funding the study?
University of Medicine and Pharmacy, Ho Chi Minh City (Viet Nam)

Who is the main contact?
Dr Thuy Pham AV

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of 0.1% chlorine dioxide mouthwash in reducing oral malodour – a 2-week randomized double-blind cross-over study

Study objectives
To assess the inhibitory effects of a mouthwash containing 0.1% ClO2 used for 2 weeks on oral malodour, periodontal status, salivary pH and flow rate, tongue coating, Gram positive and negative bacteria in saliva.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the University of Medicine and Pharmacy, Ho Chi Minh City, 15/01/2017, ref: 16142-ĐHYD, 186/ĐHYD-HĐ

Study design
Cross-over randomized double-blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Oral malodour/halitosis

Interventions
The experimental sample was commercial mouthwash (TheraBreath® Mild Mint Oral Rinse) containing 0.1% chlorine dioxide. The control sample was 0.9% sodium chloride solution with additional flavours to imitate the taste of the experimental oral rinse. Both mouthrinse samples (experimental and control) were put into identical white opaque plastic bottles. An independent person, outside this study, labelled the bottles with code A or B for experimental or control mouthwash. Neither examiners nor subjects in the research group knew which were the experimental or control samples until the study was completed.

This study was a cross-over, randomized, double-blinded clinical trial with a 4-week wash-out period between two 2-week stages. The subjects were randomized into two groups by a person who was outside the trial. This assignment was secured secretly in the patient records, and only revealed (if necessary) after the trial ended.

In the first stage, one group was instructed to rinse with 30 mL of the experimental mouthwash twice daily (morning and evening) for 2 weeks, while the other was instructed to rinse with 30 mL of the control mouthwash in the same way. Participants were instructed to use their mouthwash in the following way: rinse with 15 mL mouthwash for 30 sec, then spit and continue to gargle with 15 mL mouthwash for 15 sec. After 4 weeks of wash-out, in the second stage, each group used the other mouthwash for 2 weeks. During the study, participants were given dentifrice without antibacterial agents to use, and continued to brush teeth in their own way. They were also not allowed to rinse with other kinds of mouthwash nor brush their tongues.

Subjects were evaluated for organoleptic scores and the amount of VSCs at baseline (T0), after 12 h (T1) and after 2 weeks (T2) of using mouthwash. PI, GI, BOP, tongue coating score, salivary pH and flow rate, and the number of salivary bacteria of species A. actinomycetemcomitans, F. nucleatum, P. gingivalis, S. moorei, S. salivarius, T. denticola and T. forsythia were evaluated at baseline (T0) and after 2 weeks of using mouthwash (T2).

Intervention Type
Other

Primary outcome measure
VSC concentration measured with hydrogen sulphide (H2S) and methyl mercaptan (CH3SH) gas analysis machine at baseline, 12 hours and 2 weeks

Secondary outcome measures
1. Organoleptic score measured directly by an examiner using 0-5 scale at baseline, 12 hours and 2 weeks
2. Plaque index (PI) and gingival index (GI) assessed using the method of Loe and Silness (Loe, 1967), and bleeding on probing (BOP) evaluated at four sites (distal, buccal, mesial and lingual) on all teeth except for third molars at baseline, 12 hours and 2 weeks
3. Evaluation of tongue coating based on the criteria of Winkel et al. (2003) at baseline, 12 hours and 2 weeks
The pH of resting saliva determined by a pH paper test (Saliva-Check Buffer Kit, GC, Japan) at baseline, 12 hours and 2 weeks
4. Detection and determination of bacterial species A. actinomycetemcomitans, F. nucleatum, P. gingivalis, S. moorei, S. salivarius, T. denticola and T. forsythia in resting saliva using a multiplex real-time polymerase chain reaction (PCR) assay at baseline and after 2 weeks

Overall study start date
01/02/2017

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. First- to third-year students at the University of Medicine and Pharmacy, Ho Chi Minh City who had halitosis as a chief complaint
2. An organoleptic score ≥ 2 based on the Rosenberg scale (Rosenberg & McCulloch, 1992)
3. A level of H2S > 1.5 ng/10 mL or CH3SH > 0.5 ng/10 mL (1) determined by OralChromaTM

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
During the study, 5 subjects were eliminated because they did not participate in the full protocol, so that the final sample was 39 participants.

Total final enrolment
39

Key exclusion criteria

1. Gastrointestinal diseases or respiratory diseases
2. Habit of smoking
3. Wearing dentures or orthodontic appliances
4. Undergoing any antibiotic treatment 1 month before and during the study course

Date of first enrolment
01/02/2017

Date of final enrolment
15/02/2017

Locations

Countries of recruitment
Viet Nam

Study participating centre
University of Medicine and Pharmacy, Ho Chi Minh City
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Sponsor information

Organisation
University of Medicine and Pharmacy, Ho Chi Minh City

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/025kb2624

Funder(s)

Funder type
University/education

Funder Name
University of Medicine and Pharmacy, Ho Chi Minh City

Results and Publications

Publication and dissemination plan
The study protocol and statistical analysis plan are available for any researchers who wish to access the data to achieve aims in the approved proposal. Please contact pavthuy@ump.edu.vn to request. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
08/09/2018

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 Pham Anh Vu Thuy (pavthuy@ump.edu.vn) for researchers who wish to access the data to achieve aims in the approved proposal. Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices) are available from 3 months to 5 years following article publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/10/2018	27/07/2020	Yes	No