

# Efficacy of 0.1% chlorine dioxide mouthwash in reducing oral malodour

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>25/02/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/03/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>27/07/2020       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data                                              |

## 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% ClO<sub>2</sub> 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

Dr Thuy Pham AV

## Contact details

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# Additional identifiers

# 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% ClO<sub>2</sub> 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

## Primary study design

Interventional

## Study design

Cross-over randomized double-blind clinical trial

## Study type(s)

Treatment

## 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(s)

VSC concentration measured with hydrogen sulphide (H<sub>2</sub>S) and methyl mercaptan (CH<sub>3</sub>SH) gas analysis machine at baseline, 12 hours and 2 weeks

## Key secondary outcome(s)

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

## 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  $\geq 2$  based on the Rosenberg scale (Rosenberg & McCulloch, 1992)
3. A level of H<sub>2</sub>S > 1.5 ng/10 mL or CH<sub>3</sub>SH > 0.5 ng/10 mL (1) determined by OralChroma™

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### 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

Faculty of Odonto-Stomatology

Ho Chi Minh

Viet Nam

700000

# Sponsor information

## Organisation

University of Medicine and Pharmacy, Ho Chi Minh City

## 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

## 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](mailto: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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 23/10/2018   | 27/07/2020 | Yes            | No              |