

# The effect of different commercially available mouthwashes with active ingredients in a group of systemically and periodontally healthy subjects with intra-oral halitosis.

## A three week, single-center, single-blind, four-arm randomized controlled clinical trial

Published: 26-10-2023

Last updated: 07-12-2024

Primary Objective: The aim is to evaluate, among in a group of systemically and periodontally healthy subjects, the effect of four different (commercially available) oral mouthwashes with intra-oral halitosis. In particular, what is the effect of...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56598

### Source

ToetsingOnline

### Brief title

Clinical halitosis mouthwash study. RCT

### Condition

- Other condition

**Synonym**

Bad breath and breath odor

**Health condition**

Intra-orale halitosis

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** ACTA Dental Research B.V.

**Source(s) of monetary or material Support:** ACTA Dental Research B.V., Viatris

**Intervention**

**Keyword:** Intra-oral halitosis, Mouthwashes with active ingredients, Negative control (water), Tongue coating

**Outcome measures****Primary outcome**

Main study parameter/endpoint;

- The main study parameters is the hydrogen sulphide measured by the OralChroma.

**Secondary outcome**

Secondary study parameters/endpoints;

- Methyl mercaptan concentrations (ppb) measured by the OralChroma.
- The total oral sulfide concentration will be measured with the Halimeter device.
- Breath odor intensity with organoleptic scores.
- Tongue coating and tongue colour assessed with two different indices.
- Halitosis questionnaire.

- Subjects' perception.

## Study description

### Background summary

Available data indicate that 10-30% of the population may have a significant problem with intra-oral halitosis. Individuals with intra-oral halitosis present increased concentrations of volatile sulphur compounds (VSCs), such as hydrogen sulphide (H<sub>2</sub>S) methyl mercaptan (MM) and dimethyl sulphide (DMS) in air from the oral cavity. The oral cavity is considered as the major source for intra-oral halitosis. Mouthwashes containing metal salts, essential oils, chlorhexidine, chlorine dioxide and cetylpyridinium chloride have been shown to reduce VSCs. Some of these agents are also known to have an antibacterial effect. Mouthwashes with a combination of different agents, claiming to reduce intra-oral halitosis, are presently available on the market. There are, however, few randomized controlled trials comparing the effectiveness of different mouth rinses on intra-oral halitosis.

### Study objective

Primary Objective:

The aim is to evaluate, among in a group of systemically and periodontally healthy subjects, the effect of four different (commercially available) oral mouthwashes with intra-oral halitosis.

In particular, what is the effect of the commercially available mouthwash containing zinc acetate and chlorhexidine diacetate compared to

- a negative control (water),
- to a positive control mouthwash containing chlorhexidine digluconate, cetylpyridinium and
- compared to a mouthwash containing essential oils.

Three commercially available mouthwashes are without alcohol.

Secondary Objectives:

1. To evaluate the effect a mouthwash containing zinc acetate and chlorhexidine diacetate, compared to the different mouthwashes evaluating different tongue coating indices.
2. To evaluate the subject\*s perception of his/her own breath odor (baseline and end and per mouthwash).
3. To evaluate the perception of the subject\*s attitudes towards the different

mouthwashes used in this study.

## Study design

A three week, single-centre, single-blind, four arm randomized controlled clinical trial with four different groups.

## Intervention

There will be four groups;

1. Mouthwash of CB12® (alcohol free) with active ingredients; 0.03% zinc and chlorhexidine (0.025%).
2. Negative control group: water of Bar-le-Duc.
3. Positive control group: mouthwash Halita® (alcohol free) with the active ingredients 0.05% cetylpyridinium chloride, 0.14% zinc and 0.05 chlorhexidine.
4. Comparison mouthwash: Listerine® Cool Mint (alcohol free) with active ingredients essential oils.

All groups will use the same commercially available regular fluoride dentifrice.

## Study burden and risks

Neither immediate nor long-range physical risks are involved.

## Contacts

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# **Trial sites**

## **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- adults  $\geq 18$  of age
- classified as systemically healthy assessed by a medical questionnaire; no systemic diseases
- - periodontally healthy classified according to the Periodical Periodontal Screening (PPS) tool: PPS 1 or PPS 2 with not more than 2 sites with probing pocket depths of 5mm
- have a minimum of 20 natural teeth
- having finished the necessary dental treatment(s)
- regular visit of the dentist in the past 6 months - 12 months
- intra-oral halitosis at screening (visit 1) and at baseline (visit 2 - day 0);
  - o hydrogen sulfide  $>112$  ppb as measured by OralChroma and
  - o total volatile sulfur compound level  $>160$  ppb as determined with a Halimeter
  - o oral organoleptic score  $\geq 2$
- self-reported halitosis

### **Exclusion criteria**

- allergy or hypersensitive to any of the ingredients of the products;
  - o zinc acetate
  - o chlorhexidine diacetate
  - o cetylpyridinium chloride
  - o essential-oils
  - o fluoride
- smoking or quitted smoking  $<1$  year before the screening appointment
- PPS 2 with  $> 2$  sites with a probing pocket depth of 5mm

- PPS 3
- open carious lesions
- dental students or dental care professionals
- self-reported pregnancy and/or lactating
- systemic medication related to oral dryness
- systemic antibiotic therapy within the preceding 3 months
- smoking or stopped smoking within 1 year before the screening
- extra-oral halitosis
- night guard
- orthodontic brackets (retainer is allowed)
- removable prosthesis
- oral piercings

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	09-11-2023
Enrollment:	68
Type:	Actual

## Ethics review

Approved WMO	
Date:	26-10-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL81289.018.23