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

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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...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	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 (H2S) 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 >= 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 depts 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 >=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 quidded smoking <1 year before the screening appointment
- PPS 2 with > 2 sites with a probing pocket dept 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