

# The effect of chemotherapeutic agents and mechanical tongue cleaning on morning bad breath

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The aim of this study was to investigate the effect of an antiseptic mouthwash and tongue hygiene on the concentration of volatile sulphur compounds and morning bad breath in periodontal healthy subjects.

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

## Summary

### ID

NL-OMON36247

### Source

ToetsingOnline

### Brief title

Effect of chemotherapeutic agents and mechanical tongue cleaning on MBB

### Condition

- Other condition

### Synonym

Morning Bad Breath (MBB)

### Health condition

Slechte ochtend adem

### Research involving

Human

## Sponsors and support

**Primary sponsor:** ACTA dental research B.V.

**Source(s) of monetary or material Support:** GABA International ,Industrie: GABA International

## Intervention

**Keyword:** Morning bad breath, Mouthrinse, Tongcleaning

## Outcome measures

### Primary outcome

The primary outcome is morning Bad Breath and will be measured by three different methods

Organoleptic score:

The judge is using an arbitrary 0-5 scale (Rosenberg et al. 1991a, Rosenberg et al. 1991b further modified by Greenman et al. 2004). The 0 represented absence of odour, 1 was given for barely noticeable odour, 2 for slight odour, 3 for moderate odour, 4 for strong odour and 5 for extremely strong odour.

Halimeter:

We are using a portable industrial sulphide monitor (Halimeters, Interscan Corp., Chatsworth, CA, USA). The unit is zeroed to ambient air before each measurement, using the technique established by Rosenberg et al. (1991a, b).

OralChroma assessments:

A portable gas chromatography (OralChroma®) using a flame photometric detector is the preferable method if precise measurements of specific gases are

required. This technology is specifically designed to digitally measure molecular levels of the three major VSC (H<sub>2</sub>S, CH<sub>3</sub>SH, and dimethyl sulfide CH<sub>3</sub>SCH<sub>3</sub>).

## **Secondary outcome**

Tongue coating index:

The procedure to assess coating is a modification of the method as described by Miyazaki et al. (1995) and described in detail by Mantilla Gomez et al. (2001).

Enquete: subjects give their opinions about their experience of this clinical trial

## **Study description**

### **Background summary**

Halitosis is a general term used to describe an unpleasant or offensive odor emanating from the oral cavity. Several (non-oral) pathological conditions have been related to oral malodor, including infection of the upper and lower respiratory tracts, the gastrointestinal tract, and some metabolic diseases involving the kidneys or the liver (Manolis 1983). However, clinical surveys have shown that around 90% of all bad breath odors originate in the mouth (Delanghe et al. 1997). Oral halitosis is the specific term used to define halitosis with an origin within the oral cavity

### **Study objective**

The aim of this study was to investigate the effect of an antiseptic mouthwash and tongue hygiene on the concentration of volatile sulphur compounds and morning bad breath in periodontal healthy subjects.

### **Study design**

This is a parallel blind, randomized, clinical trial of 3 months  
The trial will take 3 weeks for each person.

## Intervention

The control group: use fluoride toothpaste Everclean ® HEMA, which is available on the market.

Intervention (test) group: use Meridol ® Halitosis: toothbrush, toothpaste, mouthwash and tongue cleaner.

## Study burden and risks

There are no risks involved.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

\* \* 18 years - 35 years \* minimum of 20 natural teeth \* Non-smokers \* Organoleptic mean score of minimum 2

## Exclusion criteria

\* Open active caries \* absence of probing depth \* 5mm probing and attachment loss \* 2 mm \* the absence of pregnancy- breastfeeding and systemic diseases \* On medications which can cause malodour \* the absence of antibiotic in the last 2 months \* participation in a clinical study within the previous 30 days \* Ongoing dental treatment or any other medical treatment of the oral cavity

## Study design

### Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2012
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO

Date:	18-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	20-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	31-05-2012
Application type:	Amendment
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

ID: 24468  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL34505.018.11
OMON	NL-OMON24468