

The effect of rinsing or drinking water on Morning Bad Breath (MBB).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28921

Source

NTR

Brief title

Waterslot

Health condition

Morning Bad Breath, drinking water and rinsing with water

Sponsors and support

Primary sponsor: Acedemic Center Dentistry Amsterdam (ACTA)

Source(s) of monetary or material Support: Self funded

Intervention

Outcome measures

Primary outcome

The primary outcome is Moring Bad Breath (MBB) and will be measured by three different methods:

1. 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;

2. 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);

3. 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 (H₂S, CH₃SH, and dimethyl sulfide CH₃SCH₃).

In total there will be three different measurements to express the level of MBB.

Secondary outcome

1. 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);

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

Study description

Background summary

To reduce the Morning Bad Breath (MBB) several websites suggest that rinsing or drinking water upon awakening is effective. Since MBB can be caused by a dry mouth. Water drinking help to stimulate the saliva production and saturate the whole mouth. Rinsing seems like the obvious first-aid measure to take (consumer websites). This home-remedy is however not supported with scientific evidence.

Study objective

The purpose of the study is to assess the effect of a rinsing or drinking water on the MBB in

periodontally and systemically healthy subjects.

Study design

Single visit with pre and post measurements.

Intervention

The study is designed as a single - blind (examiner) randomized two-arm parallel clinical trial. Pre- and post measurements will be carried out:

1. The control group will rinse with 15 milliliter water for 30 seconds;
2. The intervention group will drink 200 milliliter water.

Contacts

Public

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Eligibility criteria

Inclusion criteria

1. > 18 years;
2. Systemic healthy, assessed by medical questionnaires;
3. Non smokers;
4. No orthodontic appliances;
5. No removable (partial) dentures;
6. Minimum 20 teeth;
7. No caries;
8. Willing and able to give a written informed consent;
9. Willing to adapted the style rule for 48 hours.

Exclusion criteria

1. Any pathological alterations of the oral mucosa/ pregnancy;
2. Participation in a clinical study within the previous 30 days;
3. Acute sinusitis or severe oral- pharyngeal infections;
4. On medications which can cause malodor;
5. Reduced salivary flow due to pathological reasons (e.g. Sjögren syndrome);
6. Subjects unwilling to abstain from additional oral hygiene (only tooth brushing allowed) particularly mouthrinse, chewing gums, flossing, peppermint containing product etc. and alcohol 12 hours prior the first measurement at the study site and until the completion of all measurements.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	29-11-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-01-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35237
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3101

Register

NTR-old

CCMO

ISRCTN

OMON

ID

NTR3241

NL38260.018.11

ISRCTN wordt niet meer aangevraagd.

NL-OMON35237

Study results

Summary results

N/A