

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

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The aim of the study is 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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24468

Bron

NTR

Aandoening

Morning Bad Breath, tongue cleaning and mouthwash

Ondersteuning

Primaire sponsor: Academic Center Dentistry Amsterdam (ACTA)

Overige ondersteuning: GABA International

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

A daily fresh morning bad breath is often not feasible. Chemotherapeutic agents and tongue cleaning as an adjunct to mechanical plaque control would be valuable.

Meridol® Halitosis has shown to be an effective product on the concentration of volatile sulphur compounds and morning bad breath. Up to now the combination of the Meridol halitosis tooth & tongue gel, mouthrinse, tongue cleaner and toothbrush are lacking.

Doel van het onderzoek

The aim of the study is 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.

Onderzoeksopzet

Time points:

1. Screening;
2. Visit 1: day 0;
3. Visit 2: day 1;
4. Visit 3: day 7;

5. Visit 4: day 21.

Onderzoeksproduct en/of interventie

After selection subjects are randomly divided among a test or control group. Subjects receive supervised instruction how to use their products.

1. The test group use: Meridol Halitosis tooth & tongue gel, meridol Halitosis toothbrush (twice a day), meridol Halitosis tongue cleaner (once a day), meridol Halitosis mouthrinse (twice a day);

2. The control group use: standard toothpaste (Hema brand), meridol Halitosis toothbrush (twice a day).

Clinical measurement are performed at day 0/baseline, day 1, day 7, day 21.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. > 18 years - 35 years;
2. Minimum of 20 natural teeth;
3. Non-smokers;
4. Organoleptic mean score of minimum 2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Open active caries;
2. Absence of probing depth > 5mm probing and attachment loss > 2 mm;
3. The absence of pregnancy- breastfeeding and systemic diseases;
4. On medications which can cause malodour;
5. The absence of antibiotic in the last 2 months;
6. Participation in a clinical study within the previous 30 days;
7. Ongoing dental treatment or any other medical treatment of the oral cavity.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind

Controle: Placebo

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 29-11-2011
Aantal proefpersonen: 60
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 17-01-2012
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36247
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3100
NTR-old	NTR3240
CCMO	NL34505.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36247

Resultaten

Samenvatting resultaten

N/A