# The effect of a newly developed zendium dentifrice on gingivitis and plaque. Zendium toothpaste.

No registrations found.

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

## Summary

### ID

NL-OMON27210

**Source**
Nationaal Trial Register

**Health condition**

Gingivitis and plaque

### Sponsors and support

**Primary sponsor:** ACTA - ADR
**Source(s) of monetary or material Support:** Sara Lee - Amersfoort

### Intervention

### Outcome measures

**Primary outcome**

1. BOMP (bleeding on marginal probing) - Van der Weijden 1994;

2. Plaque Index - Quigley & Hein 2007.

**Secondary outcome**

VAS Questionnaire about the used product.

# Study description

### Background summary

Control of plaque on the tooth surfaces is the most important method of controlling dental disease. A manual toothbrush is the most popular mechanical method of plaque control. This non-specific control of the periodontal microbiota is effective in the majority of cases where access to the plaque deposits is possible (Listgarten 1988). In spite of the activity in improving toothbrush type and design, most people reduce plaque scores only with approximately 50% when they brush their teeth (Jepsen 1998). The development of a dentifrice that would allow the average person in helping to control plaque and gingivitis would be desirable.

### Study objective

The primary objective of the present trial is to evaluate, during a 4-week period, the efficacy of a Zendium dentifrice containing enzymes, colostrum, lysozyme & zinc, in combination with the use of a manual toothbrush with respect to plaque removing efficacy, plaque growth inhibition, and effect on gingival inflammation.

### Study design

Time point:

1 visit: BOMP Plaque Index;

2 visit: BOMP Plaque Index;

3 visit: BOMP Plaque Index and VAS.

### Intervention

Group 1: Experimental zendium dentifrice based on mild enzym complex non-SLS zendium;

Group 2: Regular zendium non SLS;

Group 3: Colgate SLS dentifrice;

Group 4: Sensodyne SLS dentifrice.

The intervention will have a duration of 4 weeks in which the participants have 2 visits.

# Contacts

**Public**
Acedemisch Centrum Tandheelkunde Amsterdam (ACTA)<br>
Afdeling CPT- Parodontologie<br>
Gustav Mahlerlaan 3004
G.A. Weijden, van der

Amsterdam 1081 LA
The Netherlands
+31 (0)20 5188307
**Scientific**
Acedemisch Centrum Tandheelkunde Amsterdam (ACTA)<br>
Afdeling CPT- Parodontologie<br>
Gustav Mahlerlaan 3004
G.A. Weijden, van der

Amsterdam 1081 LA
The Netherlands
+31 (0)20 5188307

# Eligibility criteria

## Inclusion criteria

1. > 18 years;

2. Systemically healthy;

3. Minimum 5 teeth per quadrant;

4. Moderate gingivtis (40% bleeding on marginal probing);

5. Not participate in other oral clinical care study;

6. An absence of oral lesions and/or periodontal pockets ≤ 5 mm.

### Exclusion criteria

1. The absence of pregnancy and systemic diseases such as aids, cirrhosis, diabetes;

2. The absence of any adverse medical history or long-term medication;

3. Or any physical condition that limits manual dexterity.

## 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): | 15-10-2010 |
| Enrollment: | 120 |
| Type: | Anticipated |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 07-12-2010 |
| Application type: | First submission |

## Study registrations

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

ID: 34372
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL2524 |
| NTR-old | NTR2642 |
| CCMO | NL33561.018.10 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON34372 |

# Study results

**Summary results**
N/A