

# Evaluation of a dentifrice with natural ingredients in the prevention of plaque and gingivitis

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The aim of the present study was to evaluate the potential of a dentifrice with natural ingredients (Aronal®) to inhibit gingivitis development over a period of 4 months.

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

## Summary

### ID

NL-OMON30662

### Source

ToetsingOnline

### Brief title

Dentifrice with natural ingredients

### Condition

- Other condition

### Synonym

inflammation of the gingiva

### Health condition

gingivitis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** GABA International AG

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

## Intervention

**Keyword:** gingivitis, manual toothbrush, plaque, toothpaste

## Outcome measures

### Primary outcome

by standardized measurements and score procedures determine the effect of the oral hygiene procedure on levels of plaque and gingival abrasion over the evaluation period.

### Secondary outcome

nvt

## 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. In spite of the activity in improving toothbrush type and design, most people still remove only approximately 50% of the plaque present when they brush their teeth (Jepsen 1998). The development of a dentifrice that would allow the average person to control plaque and gingivitis would be desirable.

### Study objective

The aim of the present study was to evaluate the potential of a dentifrice with natural ingredients (Aronal®) to inhibit gingivitis development over a period of 4 months.

### Study design

The study is designed to evaluate the effect of a dentifrice with natural

ingredients over a period of 4 months. 80 subjects (non-dental) will be selected on the basis of having moderate gingival inflammation. The single blind study consists of 2 phases: a pre-experimental phase of 3 weeks and an experimental period of 4 months. At the start of the pre-experimental phase gingivitis (MGI) bleeding upon marginal probing (BOMP) and plaque (Quigley & Hein) will be assessed. Subjects receive a written instruction in the use of a manual toothbrush. Furthermore, a combination of Bocasan® and chlorhexidine 0.20% will be used to rinse 2 times per day during the 3 weeks prior to the second phase of the experiment. The baseline assessment is scheduled 3 weeks later. Subjects are randomly assigned to one of 2 groups (test & control). All will be instructed to brush their teeth with their assigned toothpaste for 2 minutes 2 times a day using the timer. Clinical examinations will be performed after 4 months. All parameters assessed at the start of the study are evaluated after 4 months.

### **Intervention**

Improvement of gingival health by removing plaque and avoiding gingival abrasion with the manual toothbrush and a toothpaste with natural ingredients.

### **Study burden and risks**

Risk for subjects: none.

## **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

At least 5 evaluable teeth in each quadrant

Moderate gingivitis (\*40% bleeding on marginal probing),

### Exclusion criteria

No partial dentures, orthodontic banding or wires.

No oral lesions or periodontal pockets \*5mm

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	80

Type:

Anticipated

## Ethics review

Approved WMO

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**

CCMO

**ID**

NL14928.018.06