

# Dynamic oral ecosystem

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20662

### Source

NTR

### Health condition

Gingival inflammation

## Sponsors and support

**Primary sponsor:** Prof. dr. J.R. Bausch

ACTA Dental Research B.V. (ADR)

Gustav Mahlerlaan 3004

1081 LA Amsterdam

The Netherlands

r.bausch@acta.nl

**Source(s) of monetary or material Support:** Sponsor

## Intervention

## Outcome measures

### Primary outcome

Microbiological composition

### Secondary outcome

Biochemical, immunological and clinical effects

## Study description

### Study objective

We hypothesize this difference is due to differences in the mechanisms by which the individuals can withstand and/or adapt to the stress conditions applied in the clinical model and that these mechanisms are of key importance in our ability to maintain our oral health. We expect that – in analogy of other biological systems – the mouth has intrinsic mechanisms to maintain or restore homeostasis following a perturbation. These processes have up to date gained little attention in research. By examining in detail the dynamic biological responses of the oral ecosystem in individuals during experimental gingivitis induction and relating these responses to individual variation in the inflammatory outcome, it is expected that the biological processes that contribute to our ability to maintain oral health can be identified.

### Study design

Day -14, 0, 2, 5, 9, 14, 21

### Intervention

Challenge intervention: no oral hygiene for 2 weeks

Intervention: erythritol tablets

## Contacts

### Public

W. Crielaard  
Department of Preventive Dentistry  
Academic Centre for Dentistry Amsterdam (ACTA) University of Amsterdam and VU University  
Amsterdam  
Gustav Mahlerlaan 3004  
Amsterdam 1081 LA  
The Netherlands

### Scientific

W. Crielaard  
Department of Preventive Dentistry  
Academic Centre for Dentistry Amsterdam (ACTA) University of Amsterdam and VU University  
Amsterdam  
Gustav Mahlerlaan 3004  
Amsterdam 1081 LA  
The Netherlands

# Eligibility criteria

## Inclusion criteria

- Adult,  $\geq 18$  years - 55 year
- Male and female
- Classified as systemically healthy, assessed by medical questionnaire
- Minimum of 20 natural teeth: first and second molars must be present
- Having visited the dentist for a regular check-up within the last year and having finished the necessary treatment.
- Willing and able to give written informed consent
- Willing to consent to use their collected anonymous and coded body materials for further research

## Exclusion criteria

- Anyone presenting with a dental pocket probing depth  $\geq 5$ mm with bleeding on probing and attachment loss  $\geq 2$  mm, Dutch Periodontal Screening Index score 3+/ 4
- $>40\%$  BOP
- Overt dental caries
- Smokers, definition non-smoker:  $<1$  cigarette every day for at least one year
- Removable partial dentures
- Removable night guard
- Oral and/or peri-oral piercings
- Apparent oral lesions (aphthous ulcers excluded)
- Presence of orthodontic banding (except for lingual retention wire)
- Abuse of drugs/alcohol

- ACTA dental student or ACTA professional
- Participation in a clinical study within the previous 30 days

General health and use of medication:

- Self-reported pregnancy or breastfeeding
- Use of antibiotics during the last 3 months
- Need of antibiotic prophylaxis prior to dental treatment
- Use of anti-inflammatory drugs on a regular basis
- Evidence of any systemic disease or compromised health condition
- Acute sinusitis
- Severe oral- pharyngeal infections
- Current disorders/disease resulting in (self-induced) vomiting
- Reduced salivary flow due to pathological reasons (e.g. Sjögren syndrome)
- Adverse medical history or long-term medication
- Prescribed medication (except for contraceptives - birthcontrol pills)

## Study design

### Design

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

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 12-01-2015  
Enrollment: 80  
Type: Anticipated

## Ethics review

Not applicable  
Application type: Not applicable

## 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	ID
NTR-new	NL4718
NTR-old	NTR4863
Other	: TIFNOH-001-WP2

## Study results