Estimating the boundaries for a healthy oral ecosystem in young individuals - An observational clinical study -

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37231

Source
ToetsingOnline

Brief title
Estimating the boundaries for a healthy oral ecosystem in young individuals

Condition

- Other condition

Synonym
Healthy oral cavity

Health condition

gezonde mond, tandvleesontsteking

Research involving
Human

Sponsors and support

Primary sponsor: ACTA Dental Research B.V. (ADR)
Source(s) of monetary or material Support: Ministerie van OC&W,Top Institute Food & Nutrition (TIFN) - Wageningen: als 1/3 partner in dit project.,GlaxoSmithKline,Industrie: als 1/3 partner in dit project en ACTA (eerste geldstroom) ook als 1/3 partner in dit project.,Philips Research,TNO,Wageningen Universiteit,Wrigley en Cargill

Intervention

Keyword: Estimating the boundaries, Healthy oral ecosystem, Young individuals

Outcome measures

Primary outcome

The primaire study parameter is the level of gingival inflammation (Bleeding On

Marginal Probing (BOMP) and Bleeding upon Pocket Probing (BPP)).

Secondary outcome

In total there are 20 secondairy study parameters:

1. Subjective oral health

2. Generic health-related quality of life

3. Oral health-related quality of life

4. General level of nutrition measured by the Validated Food Frequency

questionnaire:

a. Frequency of food intake

b. Macronutrients

c. Micronutrients

d. Sugar intake

e. Soft drinks

f. Energy drinks

g. Juices

5. Systolic and diastolic blood pressure

6. Pulse

7. Body temperature

8. Body Mass Index

a. Standing height

b. Body weight

9. Abdominal (Waist) circumference

10. Blood cell parameters

a. White blood cells

b. Red blood cells

11. Blood biochemical parameters

a. Cholesterol level in blood

b. Glucose level in blood

12. Oral PMN numbers and function in comparison with systemic PMN

a. Count number PMN: in saliva and in blood

b. Determine functionality of PMN: from saliva and from blood

13. Saliva

a. Flow rate

b. pH measurement saliva

c. Salivary proteome

d. Microbiological composition

e. Metabolite analyses

14. Plaque samples

a. Metabolic activity of the dental plaque from the vestibular aspect of the upper jaw

b. Microbial and micobial composition of dental plaque from the lingual aspect of the lower jaw

c. Microbial and micobial composition of the interproximal plaque

d. Microbial and micobial composition of the subgingival plaque.

e. Metagenomic profiles of plaque samples

15. Microbial and micobial ecology tongue dorsum

a. Anterior part of dorsum tongue

b. Posterior part of dorsum tongue

16. Level of calculus formation at lower front teeth

a. Calculus Volpe-Manhold index

17. Level of dental plaque

a. Modified Silness & Löe plaque index

18. Dental caries experience

a. Decayed, missed, filled teeth (DMFS)

b. International Caries Assessment and Detection System (ICDAS)

c. Dentinal occlusal and approximal caries

19. Oral malodour

a. Organoleptic score

20. Volatile Sulphur Compounds (VSC*s)

a. OralChroma outcome

b. Halimeter outcome

21. Extent of tongue coating

a. Discoloration

b. Thickness

c. Tongue body structure and shape

Study description

Background summary

Maintaining a healthy oral environment is essential for many oral functions, including e.g. chewing, tasting, social interactions and speech (Locker, 2004). Most of our knowledge concerning oral physiology is primarily based on disease parameters (progression/treatment /maintenance) and not as much on parameters of oral health.

This research project will embark on a new approach where focus is given to understanding an defining, the healthy status of the oral cavity. The project aims to identify the biological processes in the oral ecosystem responsible for maintaining oral health. An important part of the project, described in this protocol is the evaluation of the biochemical, immunological, metabolic and microbial inter-individual diversity in relation to early indicators for oral disease, including dental plaque and gingival bleeding. Such database will provide suggestions on biological interactions between the host, and the microbiota colonizing the various niches in the oral cavity as well as a possible role in the onset of dental plaque formation as well as inflammatory processes.

Detailed insight in these processes have the potential for the development of novel diagnostic tools to evaluate oral health status of an individual by oral care professionals, and relating these insights to procedures for treatment and instructions for self care.

The questions is: how can we define a healthy oral cavity in particular on parameters?

Study objective

The first question that needs to be addressed is to clarify what the distribution and interrelation is of relevant clinical microbial, biochemical and immunological parameters of the oral ecosystem in a systemically healthy (non diseased) young adult population.
This will be achieved through the creation of an integrated dataset of 250 volunteers. Such biodata provide a framework for the interpretation of deflection in the ecosystem as early indicators for changes in health status.

Study design

This study is a cross-sectional, single-center single evaluation of various health related clinical, salivary, serological and microbiological parameters of 250 healthy young adult individuals without periodontitis. After the

subjects are screened for suitability they visit the clinic twice on the same day. Clinical measurements are performed in the morning and in the afternoon.

Study burden and risks

Pain, bleed, and the formation of a hematoma ar the main said effects of blood collection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Young individuals, * 18 years - 30 year
- Male and female

- Classified as systemically healthy, assessed by medical questionnaire
- Minimum of 20 natural teeth: all first molars and second and/or third molars in the upper jaw available
- Agree to present without eating and drinking on the morning of the appointment
- Having visited the dentist for a regular check-up within the last year necessary treatment included
- Willing and able to give written informed consent
- Willing to consent to use the collected body materials anonymous and coded
- Willing to refrain from brushing 24 hours before the morning appointment.

Exclusion criteria

- Anyone presenting a probing depth * 5mm with bleeding on probing and attachment loss * 2 mm, Dutch Periodontal Screening Index score 3+/ 4
- Overt dental caries
- No interproximal restorations between the first and second or third and second upper molars
- Smokers, definition smoker: * 1 cigarette every day
- Removable partial dentures
- Removable night guard
- Oral and/or peri-oral piercings
- Ongoing dental treatment or any other medical treatment of the oral cavity
- Presence of orthodontic banding (except for lingual retention wire)
- Abuse of drugs/ alcohol
- Dental student or dental professional
- Participation in a clinical study within the previous 30 days

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2012

Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2012
Application type:	Amendment
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	ID
CCMO	NL41094.018.12