Evaluating child and maternal oral microbiota sampling methods for at home usage

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Defining which sampling site in the mouth in infants and their mothers is most reproducible as determined by the differences in microbiota composition of samples collected by a trained researcher and those collected by the mother

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

Summary

ID

NL-OMON46070

Source
ToetsingOnline

Brief title
Oral microbiota sampling at home

Condition

- Other condition

Synonym
oral microbiota

Health condition

er wordt geen aandoening onderzocht

Research involving
Human

Sponsors and support

Primary sponsor: ACTA
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: infant, microbiota, oral, reproducibility

Outcome measures

Primary outcome

Primary endpoint will be reproducibility of sampling oral sites as determined

by the differences in microbiota composition of samples collected by a trained

researcher and those collected by the mother.

Secondary outcome

Information about the feasibility such as comprehensibility of the instruction

video and sampling site will be collected.

Study description

Background summary

It is becoming more and more apparent that human microbiota influences health and disease. The oral microbiota develops during the first three years after birth, but it remains unclear what factors drive this development. Studying the oral microbiota can provide us with valuable insights in its influence on human health. Especially large scale longitudinal studies are needed to gain knowledge on this subject. Home sampling would make studying of the oral microbiota less costly and more convenient for the study subjects in these kind of studies. Although several oral sites can be used for home sampling, information on reproducibility is lacking. Besides, little is known about feasibility of oral sampling in infants. This study aims to evaluate reproducibility and feasibility of several oral sampling sites.

Study objective

Defining which sampling site in the mouth in infants and their mothers is most

reproducible as determined by the differences in microbiota composition of samples collected by a trained researcher and those collected by the mother

Study design

Observational study design

Study burden and risks

Development of oral microbiota can only be studied in infants, since oral microbiota develops in the first 3 years after birth. This study is therefore group-related. The burden of taking oral microbiota samples is very low and the methods are non-invasive, so the risk of participating in the study is limited for the infants and their mothers. By participating in this study, mothers gain information on oral care for their infants, and receive a free toothbrush. We expect no adverse or serious adverse events of this non-invasive data collection. 7-9 samples will be collected per infant and mother.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

For mothers: Having an infant aged 2-4; 6-8 or 12-14 months
For infants: Being an infant aged 2-4; 6-8 or 12-14 months

Exclusion criteria

Not mastering the Dutch language
Mothers younger than 18 years old
Serious congenital abnormalities
Guardian not available for consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	16-08-2018
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	ID
CCMO	NL66102.018.18

Study results

Date completed:	22-01-2019
Actual enrolment:	60

Summary results
Trial is onging in other countries