The influence of different restorative materials on recurrent caries lesion formation and on plaque acid formation and composition.

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To determine the difference in secondary caries lesion development in tooth samples with simulated restorations from different restorative materials and to relate this to the microbial composition and acid production capacity of biofilm taken from…

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

Summary

ID

NL-OMON36255

Source
ToetsingOnline

Brief title
Recurrent caries associated with different restorative materials.

Condition

- Other condition

Synonym
cavities next to fillings, secondary caries

Health condition

cariës

Research involving

Human

Sponsors and support

Primary sponsor: Tandheelkunde
Source(s) of monetary or material Support: National Institutes of Health USA (gedeeltelijk)

Intervention

Keyword: in situ, recurrent caries, restorative materials

Outcome measures

Primary outcome

Lesion depth and integrated mineral loss of (recurrent) caries lesions

Secondary outcome

Biofilm composition and acidogenicity

Study description

Background summary

The presence of a non-biological material when a restoration is placed may influence the secondary caries process in several ways. The material properties, such as a lack in buffering capacity, may influence the development and composition of the biofilm and/or the chemical process.

Study objective

To determine the difference in secondary caries lesion development in tooth samples with simulated restorations from different restorative materials and to relate this to the microbial composition and acid production capacity of biofilm taken from those samples. The effect of antibacterial components of the material will be evaluated.

Study design

A mono-center, single-blind in situ study, with split mouth design.

Study burden and risks

The burden for participating volunteers exists of wearing a (copy) lower denture in which tooth samples are placed during a period of 8 weeks. During this time they will have to dip the denture in sucrose solution several times per day. They will visit the laboratory site once every 4 weeks. Swallowing one of the tooth samples is a relative risk, however, this has never occurred in a previous study (NL 28303.091.09).

Contacts

Public
Selecteer

Postbus 9101
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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

>= 18 years and <=75 years
healthy (no disease, no medication, ASA I)
wearing denture
Persons with salivary flow al least within normal range (unstimulated >= 0.2 ml/min; chewing

stimulated >= 0.7 ml/min)

Exclusion criteria

Persons under medication that affects immunological system or salivary glands.
Persons with systemic diseases influencing oral and salivary function.
Seriously ill persons (ASA > 2)

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2012
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	28-07-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-11-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL33526.091.11