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Caries diagnostic using dental plaque and next generation sequencing

Submission date	Recruitment status	[ ] Prospectively registered
03/01/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/01/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/01/2017	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental caries, or cavities, are one of the most common long-term health conditions worldwide. They are thought to be caused by a buildup of bacteria on the tooth surface (biofilm), which produces substances that lead to tooth decay. It is still a challenge for dentists to assess current caries in a patient, as it is only after a few months that the damage to the tooth becomes visible. There is evidence to suggest that it is not the presence of bacteria alone that leads to caries but the type of bacteria present. The aim of this study is to compare the composition of biofilms (bacteria) living in the mouths of people suffering from caries and those who are not.

Who can participate?
Healthy adults with three or more caries in need of treatment and healthy adults without caries who have had no new fillings in the last two years.

What does the study involve?
For eight hours, participants are asked to wear a mouth piece made from cattle teeth on their upper jaw so that a biofilm can form undisturbed. Samples of saliva in the mouth are taken after two, four and eight hours. These are then tested in the laboratory in order to assess the bacteria living in the both, which is then compared between the participants with caries and those without.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
1. Clinic of Operative Dentistry, Periodontology and Preventive Dentistry, Saarland University Medical Center (Germany)
2. Policlinic of Operative and Pediatric Dentistry, Carl Gustav Carus TU Dresden (Germany)

When is the study starting and how long is it expected to run for?
July 2009 to September 2016

Who is funding the study?
Deutsche Forschungsgemeinschaft (Germany)

Who is the main contact?
Professor Stefan Rupf
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HA 5192/7-1, HA 2718/11-1, RU 866/2-1

Study information

Scientific Title
Comparison of initial oral microbiomes of caries actives and caries inactives using a dynamic in situ biofilm model in young adults

Study objectives
The aim of this study is to compare the microbial composition in caries active and caries inactive adults for 2, 4 and 8 hours in in situ biofilms and saliva.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Ethics Committies of the Saarland University, 03/09/2009, ref: Sn52/05/2009
2. Dresden University, 19/10/2012, ref: EK275092012

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Only available in German and not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dental caries

Interventions
Twenty-seven volunteers are enrolled in the study, 14 caries active individuals with at least three active dentin caries lesions and 13 caries inactive individuals.

Polished bovine enamel slabs mounted in buccal direction on acrylic splints are worn by all volunteers in their upper jaws for in situ biofilm formation for eight hours and 1 ml of unstimulated saliva is collected after two, four and eight hours from each individual. Amplicon sequencing of the V1 and V2 variable regions of the 16S rRNA gene is performed on saliva samples using MiSeq. Differentially abundant operational taxonomic units (OTUs) are identified using the Wilcoxon-Mann-Whitney test. Random forests are used for sample classification and evaluated by cross-validation.

Intervention Type
Genetic

Primary outcome measure
Differences in the biofilms are assessed by amplicon sequencing of the V1 and V2 variable regions of the 16S rRNA gene using MiSeq on samples collected at 2, 4 and 8 hours.

Secondary outcome measures
No secondary outcome measures

Overall study start date

01/07/2009

Completion date
16/09/2016

Eligibility

Key inclusion criteria
Test group caries active:
1. Aged between 18 and 45
2. Minimum 24 teeth
3. Written informed consent
4. Recruitment in the outpatient departments of Saarland and Dresden Universities
5. Sufficient oral hygiene (plaque index < 50%, bleeding index < 15%)
6. Three or more active caries lesions (need of invasive treatment)

Control group caries inactive:
1. Aged between 18 and 45
2. Minimum 24 teeth
3. Written informed consent
4. Recruitment in the outpatient departments of Saarland and Dresden Universities
5. Sufficient oral hygiene (plaque index < 50%, bleeding index < 15%)
6. No active caries lesions, no new fillings within the last 2 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Smokers
2. Pregnancy
3. Drug use
4. Periodontal disease
5. Other oral diseases except caries
6. Other diseases and conditions

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Saarland University Medical Center
Clinic of Operative Dentistry, Periodontology and Preventive Dentistry
Building 73
Homburg
Germany
66421

Study participating centre
Policlinic of Operative and Pediatric Dentistry
Carl Gustav Carus TU Dresden
Fetscherstraße 74
Dresden
Germany
01307

Sponsor information

Organisation
Deutsche Forschungsgemeinschaft

Sponsor details
Kennedyallee 40
Bonn
Germany
53175

Sponsor type
Research organisation

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
16/09/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Stefan Rupf (stefan.rupf@uks.eu)

IPD sharing plan summary
Available on request