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Composition of stimulated and unstimulated saliva in subjects with inactive and active caries

Submission date
22/01/2023

Recruitment status
No longer recruiting

Registration date
06/02/2023

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental caries are considered the most prevalent human disease and affect about one third of the global population. This disease is an expensive chronic illness to treat impacting on people's quality of life because it affects psychological and social aspects of daily life beyond functional ones. This study aims to analyze if differences in saliva composition and properties from caries-inactive or active subjects affect the severity and speed of caries development.

Who can participate?
Participants aged between 18-35 of both sexes with no systemic diseases, with good general and oral health, and not using fixed or removable orthodontic devices.

What does the study involve?
Participants taking part in the study will be allocated to one of two groups: a control group and an intervention group after clinical and radiographic diagnosis. Participants in the control group (caries-inactive group) will receive preventive treatment (dietary counseling, professional dental cleaning, sealants and the application of fluoride varnish). Participants in the intervention group (caries-active group) will receive the same treatment plus placement of restorations in teeth with cavitated lesions. In the first appointment, all participants will be asked to answer questionnaires to assess socio-economic-cultural data, oral hygiene and diet. Unstimulated and stimulated saliva (each subject who will chew paraffin film) will be collected for 15 and 10 min respectively. Saliva collection will be made in the morning before any meal in three different phases: at the beginning of the study, one and three months of the study. This will allow us to see if there are any composition differences in saliva between the participants in the two study groups.

What are the possible benefits and risks of participating?
All participants will receive dental treatment after taking part in the study. Participants will benefit from receiving an oral hygiene kit (a case with a soft bristle brush, toothpaste, and dental floss), radiographic examinations for diagnosing dental caries, low complexity dental treatment (diet counseling, professional dental cleaning, sealants, application of fluoride varnish and placement of restorations in teeth with cavitated lesions when indicated). Risks remain low, but participants could feel the inconvenience of 8 hours of fasting prior to saliva collection

(everyone will receive a healthy snack after saliva collection). In addition, there is a low risk with any dental treatment: allergies to the different materials occupied during the treatment (glove material, anesthesia, time with the mouth open can cause pain in the joint, etc). Participants will also be required to attend three one-hour appointments at the dental clinics of the University of Talca for saliva collection.

Where is the study run from?
Dental clinics of the University of Talca (Chile)

When is the study starting and how long is it expected to run for?
April 2019 to August 2023

Who is funding the study?
Chilean National Agency for Research and Development (ANID) Grant no. 11190607

Who is the main contact?
Dr. Juliana Botelho (jbotelho@utalca.cl)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Protein, microbial and biochemical composition of stimulated and unstimulated saliva in young adults with inactive and active caries

Study objectives
The saliva of caries-inactive patients contains a greater proportion of potentially protective factors, resulting in absence of caries disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/10/2019, Bioethics Committee of the University of Talca (University of Talca, 2 Norte 685, Talca, Chile; +56 71 220 3065; cec@utalca.cl), ref: 23-2019

Study design

Unblinded single-centre interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prevention and treatment of dental caries in caries-inactive and active adults

Interventions
Patients with dental caries display distinctive physiochemical alterations of saliva and research into the relationship between salivary composition and caries activity has been inconclusive. This unblinded, single-centre and interventional study will recruit 40 systemically healthy adults aged between 18 and 35 years old who are attending the dental clinics of the University of Talca, Talca, Chile. Participants will be invited to participate after the screening procedure by a single trained researcher using radiographic and clinical examinations (ICDAS criteria will be applied for caries evaluation). Subjects with inactive caries will be without caries lesions and subjects with active caries will have a minimum of four cavitated carious lesions coded as 5 or 6 ICDAS. If accepting to participate, subjects will sign an informed consent form and answer questionnaires to assess socio-economic-cultural data, and oral hygiene habits and complete a food-frequency diary.

Participants in the control group (caries-inactive group) will receive preventive treatment (dental hygiene kit with dental floss, soft bristle toothbrush and toothpaste, dietary counseling, professional dental cleaning, sealants and the application of fluoride varnish).

Participants in the intervention group (caries-active group) will receive the same treatment plus placement of restorations in teeth with cavitated lesions.
Blinded statistical analysis of all data will be completed.

Procedures: Saliva (unstimulated) is collected for 15 minutes. To stimulate saliva production, the subject chews paraffin film and stimulated saliva is collected for 10 minutes. Saliva collection will be made in the morning before any meal in three different phases:
1. Baseline sample: diagnosis phase and then the subjects will be allocated into one of the experimental groups
2. One month of treatment for the caries-active group (intervention group) and the inactive-caries group (control group): after diet counseling (focused on sugar consumption), professional

dental cleaning, resin-based pit and fissures sealants and application of fluoride varnish
3. Three months of treatment: after placement of restorations in teeth with cavitated lesions using minimal intervention approaches

All preventive treatment is provided by two trained and supervised dental students. All interventions of the caries-active group will be provided by the principal investigator and/or for the necessary specialists (endodontist, prosthodontist and/or periodontist).

The subject will be offered different appointments for their individual treatment in the Dental clinics of the University of Talca (Chile).

For treatment or saliva collection the subjects will be scheduled an appointment at the Dental clinics of the University of Talca (Chile).

In the first appointment, each subject will answer questionnaires for 10 minutes and then unstimulated and stimulated saliva will be collected. The two other saliva collections (one and three months of the study) will be completed in 25 minutes. After saliva collection subjects will receive a healthy snack each time.

In the intervention group, the individualized and minimally invasive treatment proposed to each subject will be according to their needs.

Subjects will have a personal phone number and email of the principal investigator and will be instructed to contact them in case of doubts, any intercurrence or problem on any day or at any time.

Inorganic and biochemical composition will be obtained and will be compared (control and treatment group) by one-way ANOVA, followed by the Tukey test. For ANOVA, the data will be transformed when necessary and the significance level will be set at 5%.
Proteomic profiles will be obtained and then preprocessed to generate a matrix of peak intensities. The most relevant peaks will be selected using the correlation-based feature subset selection method (CFS) implemented in the Weka software. To explore and compare spectra in multidimensional space, principal component analysis (PCA) will be performed using the R packages FactoMineR and factoextra.

Intervention Type
Procedure/Surgery

Primary outcome measure
Identification of potential protective factors in unstimulated and stimulated saliva from caries-inactive and active subjects using mass spectrometry-based proteomics at baseline, one and three months

Secondary outcome measures
Characterization of unstimulated and stimulated saliva from caries-inactive and active subjects at baseline, one and three months based on:
1. Inorganic and biochemical composition measured using commercial laboratory kits
2. Protein and microbial composition measured using mass spectrometry-based proteomics

Overall study start date
02/04/2019

Completion date
01/08/2023

Eligibility

Key inclusion criteria
Systemically health adults between 18 and 35 years of age who are able to give their informed consent autonomously, with normal unstimulated and stimulated salivary flow rate, good general and oral health, ability to comply with the experimental protocol, no antibiotic use during the three months before the study and not using a fixed or removable orthodontic or devices.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Subjects with systemic diseases related with caries that affect the salivary flow (such as Sjögren's syndrome), who has periodontal diseases (except gingivitis), who that had taken antibiotics during the last three months, that regularly consumed alcohol or that takes medications daily known to alter salivary flow and smokers will be excluded from the study

Date of first enrolment
01/02/2023

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
Chile

Study participating centre

Dental clinics of the University of Talca
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Sponsor information

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Agencia Nacional de Investigación y Desarrollo

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Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

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

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Dr Juliana Botelho, jbotelho@utalca.cl at the end of the study. The datasets generated during the current study will be published as a supplement to the results publication (if requested).

The type of data that will be shared will be data for statistical analysis and meta-analysis.
Data will be available from 9 months and ending 36 months following article publication
Participants will receive a number and all analyses will be done with this number and all analyses will be blinded.
Data from individuals will not be published, just using group data.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication