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Evaluation of the role of saliva in the diagnosis of disease

Submission date	Recruitment status	[ ] Prospectively registered
08/10/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/10/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/10/2023	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Saliva is a vital biological fluid that has all the advantages of being an excellent diagnostic tool. It is easy to collect and transport, requires a simple experience to take, safe and acceptable, and contains many vital elements that can be measured by various diagnostic techniques and similar to those used in blood tests. Many researchers have attempted to find salivary biomarkers for oral and systemic diseases using different protocols and techniques. This paper aims to study salivary biomarkers that related to oral diseases such as oral squamous cell carcinoma, lichen planus, recurrent oral stomatitis, and gastrointestinal diseases such as celiac disease.
The study aims to investigate the level of LDH in the blood and in saliva of patients with squamous cell oral cancer, and the level of Cortisol in the blood and in saliva of patients with lichen planus, and also the level of IgA in the blood and in saliva of patients with recurrent oral stomatitis and celiac disease.

Who can participate?
Adults aged 18 years or older with oral squamous cell carcinoma, lichen planus, recurrent oral stomatitis, celiac disease, and healthy controls.

What does the study involve?
Pariticipants provide a saliva sample and complete a questionnaire.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
February 2018 to January 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
208

Study information

Scientific Title
Evaluation of the role of saliva in the diagnosis of oral and systematic diseases (a case-control study)

Acronym
ESRDOS

Study objectives
1. The value of the salivary LDH changes in patients with oral spiny cell carcinoma, and the value of the LDH itself changes in the blood.
2. The value of the salivary cortisol changes in patients with lichen planus, and its value changes in the blood.
3. The value of salivary IgA changes in patients with recurrent oral thrush, and its value in the

blood also changes.
4. The value of salivary IgA changes in patients with celiac disease, and its value changes in the blood.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2018, The scientific research committee of the faculty of dentistry of Damascus University (Mazzeh highway, Damascus, -, Syria; +963 1133923192; info@damascusuniversity.edu.sy), ref: 208

Study design
Observational case-control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Evaluation of saliva role in diagnosis of oral cancer, lichen planus, aphthous stomatitis and celiac disease.

Interventions
Patients were included after performing an oral and histological examination to confirm the diagnosis of specific disease and obtaining a written consent from each patient. In addition, demographic details including age, gender, smoking habits and educational level were obtained. in lichen planus group participants answered the Beck Depression Rate Questionnaire (Beck). Subsequently, blood and saliva samples were collected from the individuals of both the study group and the control group between 8:00 am and 9:00 am to measure the morning cortisol level in lichen planus group and to measure LDH oral cancer group and to measure IgA in both of aphthous stomatitis and celiac disease groups.

Intervention Type
Other

Primary outcome(s)
Measured at a single time point:
1. In the lichen planus group, cortisol was measured using an ELIZA test and then the amount of optical absorbance is measured at a wavelength of 450nm.
2. In the oral cancer group LDH was measured using the Hitachi 911 automated clinical chemistry analyzer, utilizing pyruvate as a substrate at 37 °C.
3. In both aphthous stomatitis and celiac disease groups IgA was measured using the Hitachi 912 machine.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date

07/01/2023

Eligibility

Key inclusion criteria
1. Age is over 18 years old
2. Oral squamous cell carcinoma, lichen planus, recurrent oral stomatitis, celiac disease.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Systemic diseases: such as diabetes, cardiovascular disease, renal disease, liver disorders and hypertension
2. On regular medications
3. Suffers from any mental disorder or any physical disability

Date of first enrolment
10/10/2018

Date of final enrolment
25/09/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh highway

Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication