

Evaluation of the role of saliva in the diagnosis of disease

Submission date 08/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/10/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Participants 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?

Dr Aliaa Alshaar, aliaa.alshaar@damascusuniversity.edu.sy

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 (Mazzeah highway, Damascus, -, Syria; +963 1133923192; info@damascusuniversity.edu.sy), ref: 208

Study design

Observational case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Dental clinic, Laboratory

Study type(s)

Diagnostic

Participant information sheet

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 measure

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.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

10/02/2018

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

70

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

Mazzeah highway

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Sponsor information

Organisation

Damascus University

Sponsor details

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Sponsor type

University/education

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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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date**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