

Measuring inflammatory markers in the saliva of patients with mouth lesions and skin with mouth lesions together related to lichen planus

Submission date 06/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/05/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/05/2025	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Lichen planus (LP) is a long-term immune-related condition that can affect the skin and mucous membranes, including the inside of the mouth. When it affects the mouth, it is called oral lichen planus (OLP), and when it also affects the skin or other areas, it is called mucocutaneous lichen planus (MCLP). This condition can cause painful sores, white patches, and discomfort, and in some cases, it has the potential to turn into more serious diseases. The exact cause of LP is not fully understood, but it may be related to problems with the immune system and psychological factors like stress and anxiety.

This study aims to measure the levels of three specific proteins called cytokines in the saliva of patients with OLP and MCLP. These proteins (interleukin-6, interleukin-1-beta, and interferon-gamma) are involved in inflammation and immune responses. By comparing the levels of these cytokines in patients and healthy individuals, the researchers hope to understand how these proteins relate to the disease's severity and whether they could be used as early markers of disease or indicators of how serious it is.

Who can participate?

The study will involve both men and women who are diagnosed with OLP or MCLP, confirmed both clinically and through lab tests. Participants should not be currently using treatments like corticosteroids or immunosuppressants and must not have taken any such medication for at least 1 month before the study. Healthy individuals with no history of systemic or oral disease and who are not taking any medications will also be included as a control group. Participants must be adults and willing to provide consent.

What does the study involve?

Participants will be divided into three groups: one with 20 patients diagnosed with OLP, one with 20 patients with MCLP, and a third group of 5 healthy volunteers. Each participant will provide a saliva sample, which will be collected in the morning to reduce the impact of daily variations. Before sampling, participants will be asked to refrain from eating or drinking for at least 2 hours.

The saliva will be tested using a laboratory method called ELISA to measure the levels of the

three cytokines. The results will be compared across the three groups, and the researchers will also examine whether these levels are related to how severe the disease is in each patient.

What are the possible benefits and risks of participating?

Participants will not receive direct medical treatment as part of this study, but the information gained could help improve future diagnosis and monitoring of OLP and MCLP. Since only saliva samples are taken, the process is non-invasive, safe, and generally free of side effects. There are no known risks associated with the sample collection.

Where is the study run from?

This research is being carried out at Shahid Jabar Dermatology and Venerology Center and the College of Dentistry at the University of Sulaimani. The sample analysis will also involve the College of Veterinary and the Hawkary Nishtimany Laboratory Center.

When is the study starting and how long is it expected to run for?

December 2024 to February 2026

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Pardis Nawroz Hama, pardis.hama@univsul.edu.iq

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

737 college of dentistry/University of Sulaimani

Study information

Scientific Title

Evaluation of salivary levels of interleukin-6, interleukin 1-beta, and interferon-gamma in patients with oral and mucocutaneous lichen planus: a comparative study in the Sulaimani population

Study objectives

The null hypothesis (H₀):

There is no difference between the levels of salivary interleukin-6 (IL-6), interleukin 1-beta (IL-1 beta), and interferon-gamma (IFN- γ) between the oral and mucocutaneous lichen planus and the healthy group.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 16/12/2024, The ethics committee of the College of Dentistry (Madam Mitterrand street, As Sulaymaniyah, 46001, Iraq; +964 (0)7704522890; dentistry.ethics@univsul.edu.iq, ref: COD-EC-24-0054

Study design

Prospective comparative in vivo study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Oral and mucocutaneous lichen planus

Interventions

1. Assess salivary biomarkers in OLP and MCLP
2. Compare the levels of these biomarkers in the studied groups with healthy controls
3. Correlation of the salivary biomarkers with their clinical manifestation

Intervention Type

Other

Primary outcome(s)

Measured at a single timepoint:

1. Salivary levels of interleukin-6 (IL-6) measured using enzyme-linked immunosorbent assay (ELISA)
2. Salivary levels of interleukin 1-beta (IL-1 β) measured using enzyme-linked immunosorbent assay (ELISA)
3. Salivary levels of interferon-gamma (IFN- γ) measured using enzyme-linked immunosorbent assay (ELISA)
4. Disease severity assessed using clinical scoring Lichen Planus Severity Scales:

- 4.1. For oral lichen planus (OLP): Thongprasom Clinical Score (0-5 scores)
- 4.2. For cutaneous lichen planus: Physician Global Assessment (PGA)
- 4.3. Visual Analog scale (VAS) for symptoms in both

Key secondary outcome(s)

1. Correlation between salivary cytokine levels and clinical manifestations of oral lichen planus assessed by statistical analysis of ELISA results and clinical scores at completion of data collection
2. Comparison of inflammatory marker profiles between oral-only lichen planus and mucocutaneous lichen planus using statistical analysis of cytokine levels at completion of data collection

Completion date

01/02/2026

Eligibility

Key inclusion criteria

1. Patients who are thoroughly informed about the trial and willing to participate
2. Both sexes (male and female), and females not pregnant
3. OLP and MCLP will be clinically and histopathologically confirmed by a dermatologist
4. All the patients not receiving disease-modifying treatment for at least 1 month before the study like corticosteroids and immunosuppressive drugs

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Patients who refuse to participate
2. The study excluded patients with other diagnosed oral mucosal diseases and some systemic diseases, including hematological and infectious diseases, and patients with allergic conditions
3. Systemic diseases that induce lichenoid drug eruption like cardiovascular and endocrine diseases
4. Patients who had received topical or systemic treatment 1 month before the study
5. Newly diagnosed cases

Date of first enrolment

17/12/2024

Date of final enrolment

01/09/2025

Locations

Countries of recruitment

Iraq

Study participating centre

Shahid Jabar Dermatology and venereology Center

Xabat

As Sulaymaniyah

Iraq

46001

Study participating centre

College of Dentistry, University Of Sulaimani

Madam Mitterrand street

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Sponsor information

Organisation

University of Sulaimani

ROR

<https://ror.org/00saanr69>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date