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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

Registration date
21/05/2025

Overall study status
Completed

Last Edited
19/01/2026

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 (HO):
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-1β) 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
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/01/2026	19/01/2026	Yes	No