

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparative Evaluation of salivary LDH and CRP in patients with oral erosive lichenoid reaction before and after systemic corticosteroid therapy

Protocol summary

Study aim

This study aims to check whether the salivary level of Lactate dehydrogenase (LDH) and C-reactive protein (CRP) changes after systemic treatment (steroid therapy) or not.

Design

Clinical trial without control group, randomized, phase 2, 40 patients

Settings and conduct

The study will take place in the department of oral medicine, school of dentistry, medical university of Isfahan. As recommended in Burket's oral medicine, the patients will be given a dose of 0.5 to 1 mg per kg prednisolone daily for seven days followed by a reduction of 5 mg each subsequent day. Just before the beginning of treatment and after 2 and 4 weeks, salivary LDH and CRP will be measured by non-stimulating saliva sampling and at last, the pre, and post-treatment measures will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: suffering from erosive lichenoid reaction; have consent to participate in the study
Exclusion criteria: presence of inflammatory and systemic disease; presence of another oral lesion; had received treatment

Intervention groups

All participants will be gathered in one group. They all go under systemic treatment (steroid therapy) and take saliva tests before and after 2 and 4 weeks from the beginning of treatment.

Main outcome variables

Salivary LDH and CRP measured by non-stimulating saliva sampling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160126026209N2**
Registration date: **2022-06-12, 1401/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-12, 1401/03/22**

Update count: **0**

Registration date

2022-06-12, 1401/03/22

Registrant information

Name

zahra saberi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5514

Email address

zahra.saberi@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of salivary LDH and CRP in

patients with oral erosive lichenoid reaction before and after systemic corticosteroid therapy

Public title

Comparative Evaluation of salivary LDH and CRP in patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from oral erosive lichenoid reaction that has been definitely diagnosed by histopathologic diagnosis
The patient has consent to participate in the study

Exclusion criteria:

Presence of systemic and inflammatory disease (e.g. Covid disease, blood system malignancies, etc.) that affects study factors (LDH, CRP)
The patient had been receiving former treatment for the study lesion
Presence of another lesion in the patient's mouth

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **3**

Non-stimulating saliva sampling

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences School of Dentistry, St.Hezarjarib, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-04-07, 1401/01/18

Ethics committee reference number

IR.MUI.MED.REC.1401.006

Health conditions studied

1

Description of health condition studied

Erosive lichen planus

ICD-10 code

L43.8

ICD-10 code description

Other lichen planus

Primary outcomes

1

Description

the measure of salivary lactate dehydrogenase

Timepoint

measurement of lactate dehydrogenase just before the beginning of systemic treatment and 14 and 28 days after beginning the use of systemic corticosteroid

Method of measurement

Non-stimulating saliva sampling

2

Description

the measure of salivary C Reactive Protein

Timepoint

measurement of C Reactive Protein just before the beginning of systemic treatment and 14 and 28 days after beginning the use of systemic corticosteroid

Method of measurement

Non-stimulating saliva sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the patient will be given a dose of 0.5 to 1 mg per kg prednisolone daily for seven days followed by a reduction of 5 mg each subsequent day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Dental School

Full name of responsible person

Dr.Zahra Saberi

Street address

Oral and Maxillofacial medicine department, School of Dentistry, Isfahan University of Medical Sciences
School of Dentistry, St.Hezarjarib, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5514

Email

zahra.saberi@dnt.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Omid Savabi

Street address

Vice Chancellor for Research of School of Dentistry,
Isfahan University of Medical Sciences School,
St.Hezarjarib, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Saberi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Vice Chancellor for Research of School of Dentistry,
Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5514

Fax

+98 31 3792 5569

Email

zahra.saberi@dnt.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Saberi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Vice Chancellor for Research of School of Dentistry,
Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5514

Fax

+98 31 3792 5569

Email

zahra.saberi@dnt.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Saberi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Vice Chancellor for Research of School of Dentistry,
Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 5514

Fax

+98 31 3792 5569

Email

zahra.saberi@dnt.mui.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Not specified yet

When the data will become available and for how long

Not specified yet

To whom data/document is available

Not specified yet

Under which criteria data/document could be used

Not specified yet

From where data/document is obtainable

Not specified yet

What processes are involved for a request to access data/document

Not specified yet

Comments