Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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zahra saberi
Name of organization / entity
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Iran (Islamic Republic of)
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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
Isfehan
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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Omid Savabi

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

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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

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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