

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of injectable mucoadhesive polymeric scaffolds containing aloe vera gel, zinc and mycophenolate mofetil on oral lichen planus lesions

Protocol summary

Study aim

Effect of injectable mucoadhesive polymeric scaffolds containing aloe vera gel, zinc and mycophenolate mofetil on oral lichen planus lesions

Design

Clinical trials, with parallel groups, single-blinded and randomized and sampling method is random. The randomization method is simple and with number Chart. 12 people were selected and one lesion per person was considered as a control and another was considered for treatment. Control lesion, treatment with Adcortyl ointment or Triadent will be used and test lesion will be used the combination of aloe vera extract, zinc and mycophenolate mofetil.

Settings and conduct

The study will be performed in the Oral Medicine Department of Tabriz Dental School. The control lesion will be treated with Aloe vera extract, zinc and mycophenolate mofetil with routine treatment and the test lesion will be treated with routine treatment with Adcortil ointment or Triadent. .

Participants/Inclusion and exclusion criteria

Entrance: Age over 18 years, having lichen planus, willing to participate in the study, Existence of a bilateral lesion
Exclusion: Pregnant and lactating women, Systemic use of corticosteroids, High blood pressure, Smokers, All items where topical corticosteroids are contraindicated, Adjacent waste with amalgam filling, Systemic diseases

Intervention groups

The combination of three materials of aloe vera extract, zinc and mycophenolate mofetil (MFM) is used as adhesive mucosal scaffolds in oral lichen planus. On the other hand, the same patient is considered as a control group. Routine treatment with Adcortyl ointment or Triadent will be used in both groups.

Main outcome variables

Pain and burning, size of erythema and ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048057N1**

Registration date: **2020-09-04, 1399/06/14**

Registration timing: **retrospective**

Last update: **2020-09-04, 1399/06/14**

Update count: **0**

Registration date

2020-09-04, 1399/06/14

Registrant information

Name

Zahra Aghazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3328 6132

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of injectable mucoadhesive polymeric scaffolds containing aloe vera gel, zinc and mycophenolate mofetil on oral lichen planus lesions

Public title

Effect of Topical Mycophenolate, Zinc and Aloe vera in oral lichen planus ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years A patient who is diagnosed with lichen planus on pathological examination. Willingness to participate in the study Existence of a bilateral lesion

Exclusion criteria:

Pregnant and lactating women Systemic use of corticosteroids High blood pressure Smokers All items where topical corticosteroids are contraindicated, such as: uncontrolled diabetes, history of tuberculosis, gastric ulcer Adjacent waste with amalgam filling Systemic diseases

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **2**

Lichen planus lesion on one side of the buccal mucosa is considered as the case group and on the other side of the same patient as the control group.

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method is randomly available among Individuals referring to oral medicine Department of Tabriz Dental faculty. The randomization method is simple . Our tool for randomization is the randomized number chart. Furthermore, the allocation of treatment to patients is done randomly. The lesion of one side of the patient as the control group will receive Adcortil ointment and the other side as the case group will receive scaffold.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-07-05, 1399/04/15

Ethics committee reference number

IR.TBZMED.REC.1399.339

Health conditions studied

1

Description of health condition studied

Oral lichen planus

ICD-10 code

I43.8

ICD-10 code description

oral lichen planus

Primary outcomes

1

Description

Size of erythema and ulcer

Timepoint

15 days after treatment

Method of measurement

dental micrometer (colis) .

Secondary outcomes

1

Description

Pain and burning

Timepoint

15 days after receiving the drug

Method of measurement

visual analog scale (VAS)

Intervention groups

1

Description

Intervention group: The case lesion will be covered by

scaffolds containing aloe vera extract, zinc and mycophenolate mofetil

Category
Treatment - Drugs

2

Description
Control group: The control lesion will be treated with routine treatment of Adcortyl ointment or Triadent

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Oral Medicine Department, Faculty of Dentistry, Tabriz

Full name of responsible person
Zahra Aghazadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Zahra Aghazadeh

Position
Assistant Professor

Latest degree
Specialist

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available