

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of mucoadhesive form of mycophenolate mofetil on oral erosive lichen planus lesions

Protocol summary

Summary

Lichen planus (LP), a relatively common mucocutaneous disease. Activated T cells are important in the pathogenesis of LP as indicated by the dermal lymphocytic infiltrate leading to keratinocyte destruction and lesion formation. Mycophenolate mofetil (MMF), which specifically and reversibly inhibits the proliferation of activated T cells, was introduced in the treatment of autoimmune and inflammatory skin disorders. Furthermore, MMF has also been successfully used in the treatment of graft-versus-host disease (GVHD). Both GVHD and LP are characterized by activated T cells, which play a pivotal role in lesion formation. Thus, we have used MMF for the treatment of oral lichen planus (OLP). In this double blind trial, 27 patients, referring to Oral Medicine Department of Tabriz Dental School were recruited. 10 patients have bilateral ulcerative lesions of OLP and they will be enrolled in a double blind clinical trial study (group A). 17 patients which have unilateral ulcerative lesion of OLP, will be enrolled in a before-after clinical trial study (group B). The lesion size with digital culis and pain quantity with Visual Analogue Scaling (VAS) will be recorded before and after treatment. In group A, patients will be instructed to put 2% MMF mucoadhesive on one of the dried lesions and put the placebo on the other one, twice daily for 4 weeks. In group B, patients will use only 2% MMF mucoadhesive in the same manner. Results will be analyzed by McNemar's test and wilcoxon test by using of spss software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011611976N2**

Registration date: **2013-05-23, 1392/03/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-23, 1392/03/02

Registrant information

Name

Ali Taghavi Zenuz

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 5965

Email address

taghavia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research of Tabriz University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-06-20, 1392/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mucoadhesive form of mycophenolate mofetil on oral erosive lichen planus lesions

Public title

Effect of mycophenolate mofetil on oral erosive lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with erosive oral lichen planus with clinical manifestations and histopathological criteria; existence of two lesions with similar clinical appearance on the right and left buccal mucosa; patients older than 18 years of age. Exclusion criteria: not received any treatment for the lesions for at least 4 weeks ago; any factor that cause lichenoid reaction; any systemic or dermal disease which affects immune system of the patient; incidence of any adverse effect of mycophenolate mofetil during the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy of tabriz university of medical sciences

Street address

Tabriz-Golgasht street-university of medical sciences - central building no 2-3th floor

City

tabriz

Postal code

5166614713

Approval date

2013-05-04, 1392/02/14

Ethics committee reference number

9210

Health conditions studied

1

Description of health condition studied

Oral lichen planus

ICD-10 code

L43

ICD-10 code description

lichen planus

Primary outcomes

1

Description

Size of lesion

Timepoint

Baseline and after 1 month

Method of measurement

Measured by digital culis

2

Description

Pain and burning sensation

Timepoint

Baseline and weekly for one month

Method of measurement

The oral lesions will be clinically graded based on VAS grading scale

Secondary outcomes

1

Description

Adverse effects

Timepoint

Evrey week for 1 month

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention side: mucoadhesive of mycophenolate mofetil 2%,for 1month, twice daily, after breakfast at 10 & in the afternoon at 5.

Category

Treatment - Drugs

2

Description

Control side: orabase, for 1month,twice daily, after breakfast at 10 & in the afternoon at 5.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral Medicine Department- Dental Faculty-Tabriz
University of Medical Sciences

Full name of responsible person

Dr Ali Taghavi Zenuz

Street address

Tabriz- Golgasht street- Dental School- Oral Medicine
Department

City

tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Tabriz University of Medical
Sciences

Full name of responsible person

Dr Seied Kazem Shakori

Street address

Tabriz- Golgasht street- Tabriz University of Medical
Sciences- Central building no 2- 3th floor

City

Tabriz

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

Yes

Title of funding source

Deputy of Research of Tabriz University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

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

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental Faculty of Tabriz University of Medical
Sciences

Full name of responsible person

Negin Samiei

Position

Dentistry student

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

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Dental Faculty of Tabriz University of Medical
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Dr Ali Taghavi Zonuz

Position

Associated professor of oral medicine

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Negin Samiei

Position

Dentistry Student

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty