Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Ali Taghavi Zenuz
Name of organization / entity
Tabriz University of Medical Sciences
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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 sreet- 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

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

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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
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Dentistry student

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Person responsible for scientific inquiries

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Associated professor of oral medicine

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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