

# 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 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

**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**

Tabriz- Golgasht street- Faculty of Dentistry- Oral  
Medicine Department

**City**

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+98 41 1335 5965

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n.samiei@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Dental Faculty of Tabriz University of Medical  
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**Full name of responsible person**

Dr Ali Taghavi Zonuz

**Position**

Associated professor of oral medicine

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

Tabriz- Golgasht street- Faculty of Dentistry- Oral  
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taghavia@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

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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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## **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*