

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of IMOD effect on oral lichen planus

#### Protocol summary

##### Summary

This study evaluates the effect of Imod on decreasing sign and symptom of oral lichen planus lesion. It is an open-labeled, before-after study enrolling 25 patients (60 lesions) with clinical and histopathologic diagnosis of lichen planus. They are selected among the persons, presenting to the Oral Medicine Department at the Dentistry faculty in Tehran University of Medical Sciences (TUMS). Patients with systemic disease, pregnancy and any other mucosal lesions were excluded from the study. Patients received daily IMOD capsules for 90 days. The patients were examined 2 weeks, 4 weeks, 2 months, 3 months, 4 months, 5 months and 6 months after receiving the first capsule. During these sessions they asked for pain and burning sensation. The scores of the lesions were also recorded each time, based on clinical examination by researcher. Data associated with pain and burning sensation was measured, by "visual analogue scale". Measuring the level of TNF-alfa before and after using the drug is a good index for drug efficiency. TNF-alfa would be examined in the unstimulated accumulated saliva of patients. It should be done before beginning of treatment and 3 months after it.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138710291559N1**

Registration date: **2010-01-09, 1388/10/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-01-09, 1388/10/19

##### Registrant information

##### Name

Farzaneh Aghahoseini

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6611 2437

##### Email address

aghahose@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2008-03-05, 1386/12/15

##### Expected recruitment end date

2008-12-06, 1387/09/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of IMOD effect on oral lichen planus

##### Public title

Evaluation of IMOD effect on oral lichen planus

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: clinical histopathologic diagnosis of lichen planus (Lichen planus diagnosis will be made with clinical criteria, consisting of the presence of symmetric reticular or papular lesions with or without erosive/atrophic or Bullous components. Histopathologic features of oral lichen palnus are: 1) Areas of hyperparakeratosis or hyperorthokeratosis, often with a thickening of the granular cell layer and a saw-toothed appearance to the retepages. 2) Liquefaction degeneration or necrosis of the basal layer. 3) A dense

subepithelial band, shaped by infiltration of lymphocytes and macrophages. 4) Absence of dysplastic changes)  
Exclusion criteria: Any systemic disease, pregnancy and any other mucosal lesions

#### Age

No age limit

#### Gender

Both

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: 60

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Dental Research Center

###### Street address

Dentistry faculty, Tehran University of Medical Sciences

###### City

Tehran

###### Postal code

7529

##### Approval date

2017-11-21, 1396/08/30

##### Ethics committee reference number

1382/130/88/ص

### Health conditions studied

#### 1

##### Description of health condition studied

Lichen planus

##### ICD-10 code

L-43

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Clinical score

##### Timepoint

2 weekly in the first month and then monthly for 6 months

##### Method of measurement

regeration the primary scores of lesions and their changes on the follow up period as described in the matherial and methods

### Secondary outcomes

#### 1

##### Description

Pain and discomfort in the oral lesion

##### Timepoint

2 weekly in the first month and then monthly up to 6 month

##### Method of measurement

VAS scale as described in the matherial and method

### Intervention groups

#### 1

##### Description

IMOD 400 mg daily for 3 months

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Oral medicine department of Tehran University of Medical Siences

###### Full name of responsible person

Dr Aghahosseini - Dr Neda Akbary

###### Street address

Oral medicine department -Dentistry faculty of Tehran university-Ghods Ave.Keshavarz Blvd.Tehran .Iran

###### City

Tehran

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Research center of dental Science of Tehran University of medical sciences

###### Full name of responsible person

Dr Azam khorshidian

**Street address**

Research center of dental science of tehran university-  
Ghods Ave-Keshavarz Blvd-tehran-Iran

**City**

Tehran

**Grant name**

در اختیار دانشگاه علوم پزشکی تهران

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research center of dental Science of Tehran 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**

Oral Medicine Department of Tehran University of  
Medical Sciences

**Full name of responsible person**

Dr Neda Akbary Gillani

**Position**

Resident of oral medicine

**Other areas of specialty/work**

**Street address**

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Iran

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

Oral medicine department of Tehran University of  
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**Full name of responsible person**

Dr Farzaneh Aghahoseini

**Position**

Professor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**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*