

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

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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

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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

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Professor

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Web page address

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