Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Randomised Double Blind Placebo Controlled Trial of the Effect of Oral IMOD in Oral Lichen Planus

Protocol summary

Summary

The objective of this study is to study the effectiveness of oral IMOD in the treatment of Oral Lichen Planus. In this randomized, double blind placebo-controlled trial, 40 patients with diagnosis of oral lichen planus lesion will be recruited. The patients will be randomly assigned into intervention or control groups. The patients in the intervention group will receive IMOD, 120mg capsules, 4 times a day for 3 months. The patients in the control groups will receive placebo with the same dosage. The outcome measures are Pain and burning sensation, Clinical grade of lesion, Oral TNF-α, Clinical Global Impression of Change (CGIC), and Patient Global Impression of Change (PGIC).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801191559N2**
Registration date: **2010-12-21, 1389/09/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-21, 1389/09/30

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

Pars Roos Pharmaceutical Company

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-11-21, 1390/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomised Double Blind Placebo Controlled Trial of the Effect of Oral IMOD in Oral Lichen Planus

Public title

Assessing the effectiveness of IMOD in Oral Lichen Planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Presence of oral lesions of oral Lichen Planus, Clinical diagnosis of oral lesions: i.e. bilateral or symmetrical reticular lesions with or without atrophic erosive or bolus lesions, Presence of microscopic diagnostic criteria of Lichen Planus: i.e. increase in keratinisation with increase in thickness of granular cell, hydropic degeneration of basal layer, sub-epithelial infiltration of T lymphocytes, no dysplasia), Age 18 - 64
Exclusion criteria: Presence of dysplasia in histopathological view, Presence of lesion close to the amalgam filling, Presence of significant systematic disorder, History of local or systematic therapy during a month prior to the study, Pregnancy or intention of becoming pregnant during the study period (6 months),

Breastfeeding, Inability to give informed consent according to the agreed process, Any drug hypersensitivity, Receiving radiotherapy, chemotherapy or any immunosuppressive drug

Age

From **18 years** old to **64 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The patients will be allocated to the intervention or control group using a separate complete block randomisation method. Blocks of 4 will be used for this purpose. Randomisation will not be exposed to those conducting the study and will be provided in closed letters with successive numbers. The envelope will be opened when a patient is going to join the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Central Building, Ghods St., Keshavarz Blvd., Tehran, Iran

City

Tehran

Postal code

Approval date

2010-12-21, 1389/09/30

Ethics committee reference number

1175/130/89/ɔ

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

Pain and burning sensation

Timepoint

Baseline and every other week during the first month and every month during the next five month

Method of measurement

Intensity of pain and burning sensation during the previous week will be measured mainly through a 5-point rating numerical scale from no pain to very severe pain. 0 = no pain or burning sensation 1 = mild pain or burning sensation 2 = moderate pain or burning sensation 3 = severe pain or burning sensation 4 = very severe pain or burning sensation

2

Description

Clinical grade of the lesion

Timepoint

Baseline and every other week during the first month and every month during the next five month

Method of measurement

The oral lesions will be clinically graded based on the following grading scale: 0 = normal mucosa without lesion, 1 = reticular lesion with atrophic area less than 1 centimeter, 2 = reticular lesion with atrophic area more than 1 centimeter 3 = reticular lesion with erosive area less than 1 centimeter 4 = reticular lesion with erosive area more than 1 centimeter

Secondary outcomes

1

Description

Level of TNF-α in Saliva

Timepoint

Before and after the intervention

Method of measurement

To measure the TNF-α, the saliva will be collected from the patients without stimulation between 9:00 and 12:00 in the morning. The patients will be asked to pure their saliva in a pot every 60 minutes for 5-15 minutes until the volume reach to at least 2 cc. TNF-α will be measured in the saliva by using ELISA method.

2

Description

Clinical Global Impression of Change (CGIC)

Timepoint

Every other week during the first month and every

month during the next five month

Method of measurement

Through a 10-point scale on which the clinician rates the change observed in the patient's overall status since the beginning of the study.

3

Description

Patient Global Impression of Change (PGIC)

Timepoint

At the end of the treatment

Method of measurement

Through a 10-point scale on which patients themselves rate any changes observed in their overall status since the beginning of the study. The scores on this scale varies from "much improved" to "much worse"

Intervention groups

1

Description

Placebo, 1 capsule every 6 hours, for 3 months

Category

Placebo

2

Description

IMOD, 120 mg (1capsule) every 6 hours for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic, Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Dr Farzaneh Aghahosseini

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pars Roos Pharmaceutical Company

Full name of responsible person

Dr. Farzamfar

Street address

No. 568, 13th Alley, Hormozan St., Shahrak-e-Ghods, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pars Roos Pharmaceutical Company

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

Tehran University of Medical Sciences

Full name of responsible person

Farzaneh Aghahosseini

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