Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Assesment of the efficacy of methotrexate on patients with oral lichen planus

Protocol summary

Summary

The objective of this study is to investigate the effect of methotrexate on patients with oral lichen planus. This study is a single-center, interventional, non randomized, non blinded study in which placebo will not be used. The participants in this study are patients with oral lichen planus who are referred to Razi Hospital. Inclusion criteria: patients with oral lichen planus, diagnosed by clinical and pathological criteria who did not respond to topical therapy. Exclusion criteria: immunodeficiency; pregnancy; malignancy and adverse effects. The sample size is 15 patients. 7.5 mg methotraxate in the first week and 15 mg from the following week will be administered in condition of tolerance and the resolution of oral lesions is checked. 1mg folic acid per day will be administered too. treatment duration is 12 weeks. In each visit, each patient will be evaluated for leukopenia, anemia, thrombocytopenia, liver function and kidney function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121715655N2**
Registration date: **2014-06-27, 1393/04/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-27, 1393/04/06

Registrant information

Name

Vahide Lajevardi

Name of organization / entity

Razi Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 4403 3979

Email address

lajevardi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Center of the skin and blister, Tehran University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of the efficacy of methotrexate on patients with oral lichen planus

Public title

Effects of Methotrexate on oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with oral lichen planus, diagnosed by clinical and pathological criteria, who did not respond to topical therapy. Exclusion criteria: Pregnancy and breast feeding; cancer; severe and frequent infections; Hereditary or acquired immunodeficiency; leukopenia; anemia; thrombocytopenia; hepatic dysfunction; Stomach ulcers; dysplastic lesions in pathology; ulcerative colitis disease; side effects of methotraxate

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee at Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Sciences, Ghods st, Keshavarz blvd, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-09-01, 1391/06/11

Ethics committee reference number

91/130/1174 /د

Health conditions studied

1

Description of health condition studied

lichen planus

ICD-10 code

L43.8

ICD-10 code description

Other lichen planus

Primary outcomes

1

Description

The resolution of oral lesions

Timepoint

Before treatment and at two, four, eight and twelve weeks

Method of measurement

Thongprasom Scale

2

Description

Pain reduction

Timepoint

Before treatment and at weeks two, four, eight and twelve

Method of measurement

VAS (Visual Analog Scale) Pain was scored from zero to ten

Secondary outcomes

1

Description

The side effects of methotraxate

Timepoint

First, fourth, eighth and twelfth week

Method of measurement

Examination in each visit

2

Description

The Size of lesions

Timepoint

First, fourth, eighth and twelfth week

Method of measurement

Transparent grid (mm)

3

Description

Duration of disease since diagnosis

Timepoint

Before treatment

Method of measurement

Interview

4

Description

the type of lesion (ulcerative , reticular , atrophic)

Timepoint

Before treatment

Method of measurement

previous records

5

Description

The location of lesions (bucal , gingival , palatine)

Timepoint

Before treatment

Method of measurement

previous records

Intervention groups

1

Description
In this study, in the first week, 7.5 mg methotraxate per week (three tablets, 2.5 milligrams) plus 1mg folic acid per day will be administered and from the next week, 15 mg per week plus 1mg folic acid per day in condition of tolerance will be administered. Treatment duration is 12 weeks. In each visit, each patient will be evaluated for leukopenia, anemia, thrombocytopenia, liver function and kidney function.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Vahide Lajevardi

Street address
Razi hospital, vahdat Eslami st, Vahdat Eslami square, Hafez st, Tehran, Iran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University Of Medical Sciences

Full name of responsible person
Nahid Mostofi

Street address
Central Building of Tehran University of Medical Sciences, Ghods st, Keshavarz Blvd, 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
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
Razi Hospital

Full name of responsible person
Zahra Shafiee

Position
Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Assistant professor of Dermatology

Other areas of specialty/work

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Person responsible for updating data

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Medical Student

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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