

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the therapeutic effect of methotrexate in generalized lichen planus

Protocol summary

Summary

The aim of this study is the evaluation of the efficacy of methotrexate in treatment of lichen planus and use of this agent as a treatment of choice in some instance like in old ages or in the patients with diabetes or other conditions that systemic steroids are contraindicated. Twenty patients with generalized lichen planus after signing a detailed informed consent form will enroll in our study. Laboratory data's including blood counts, liver and kidney function tests will be collected at base line and photographs will be taken from all patients at first visit. The tests and photos will be repeated at 2nd, 4th, 8th week and 6th month after the beginning for evaluation of the response, compliance and adverse effects. Methotrexate (MTX), initiated at the dose of 7.5mg - 10 mg weekly , together with 1 mg folic acid daily except the day of MTX administration .the evaluation of treatment response is as follow: no response (<25%); mild response (25-75%); moderate response (50-75%) and excellent response (>75%). Inclusion criteria are: pathologically confirmed lichen planus and age between 18-75 while the exclusion criteria's are age less than 18 or more than 80 years old; pregnancy and lactation; chronic liver or kidney disease; use of systemic corticosteroids in last 6 month or application of topical steroids in last month and inability to come for follow up visits. Primary outcome measure is the rate of improvement of lichen planus

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108187287N1**

Registration date: **2011-08-18, 1390/05/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-08-18, 1390/05/27

Registrant information

Name

Farhad Malekzad

Name of organization / entity

Skin Research Center, Shohada-e-tajrish hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 1507

Email address

a_panahi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Skin Research Center, Shohad-e-tajrish hospital, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of methotrexate in generalized lichen planus

Public title

Therapeutic effects of methotrexate in generalized lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pathologically confirmed lichen planus and age between 18-75. Exclusion criteria: age less than 18 or more than 80 years old; pregnancy and lactation; chronic liver or kidney disease; use of systemic corticosteroids in last 6 month or application of topical steroids in last month and inability to come for follow up visits.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Skin Research Center Ethic Committee

Street address

Shahid Beheshti University of Medical Sciences,
Shohada-e- tajrish hospital

City

Tehran

Postal code

Approval date

2009-12-29, 1388/10/08

Ethics committee reference number

814/88

Health conditions studied

1

Description of health condition studied

Lichen Planus

ICD-10 code

L43

ICD-10 code description

Subacute (active) lichen planus Lichen planus tropicus

Primary outcomes

1

Description

Rate of improvement

Timepoint

weeks 2, 4, 8 and 6 month after treatment

Method of measurement

Questionare and photograghy

Secondary outcomes

1

Description

Liver dysfunction

Timepoint

baseline, 2 and 4 weeks after treatment

Method of measurement

Liver function test

2

Description

Bone marrow suppression

Timepoint

Baseline, 1, 2 and 4 weeks after treatment

Method of measurement

Complete Blood Count

Intervention groups

1

Description

Methotrexate tab; 7.5-15 mg/week and folic acid tab
1mg/day except the day of methotrexate

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-tajrish hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Loghman hospital

Full name of responsible person

Street address

City

Tehran

Country of origin

Type of organization providing the funding

empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin Research Center, Shohada-e-Tajrish Hospital

Full name of responsible person

Dr. Parviz Toosi

Street address

Shohada-e Tajrish Hospital, Shahr-dari St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Skin Research Center, Shohada-e-Tajrish Hospital

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Hossein Goudarzi

Street address

Evin, Shahid Beheshti University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin Research Center, Shohada-e-Tajrish Hospital

Full name of responsible person

Dr Mohammad Saeedi

Position

M.D/ Dermatology Resident

Other areas of specialty/work

Street address

shahrdari street

City

Tehran

Postal code

Phone

+98 21 2274 1507

Fax

Email

rigel_79@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin Research Center, Shohada-e-Tajrish Hospital

Full name of responsible person

Dr Farhad Malekzad

Position

Associate Professor/M.D

Other areas of specialty/work

Street address

Shahrdari Street

City

Tehran

Postal code

Phone

+98 21 2274 1507

Fax

Email

a_panahi@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Skin Research Center, Shohada-e-Tajrish Hospital

Full name of responsible person

Dr Azin Ayatollahi

Position

MD/ Dermatology resident

Other areas of specialty/work

Street address

Shahrdari Street

City

Tehran

Postal code

Phone

+98 21 2274 1507

Fax

Email

azinay@gmail.com

Web page address

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