Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 suppresion
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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Skin Research Center, Shohada-e-TajrishHospital
Full name of responsible person
Dr. Parviz Toosi
Street address
Shohada-e Tajrish Hospital, Shahrdari 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-TajrishHospital
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
Country of origin
Type of organization providing the 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 ResearchCenter,Shohada-e-Tajrish Hospital
Full name of responsible person
Dr Farhad Malekzad
Position
Associate Proffesor/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