

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of hydroxychloroquine with methotrexate in the treatment of patients with localized scleroderma

Protocol summary

Summary

This study is a randomized double-blind clinical trial aimed to compare the therapeutic effects of hydroxychloroquine with methotrexate in patients with localized scleroderma. A total of 30 patients with localized scleroderma will be randomized into two groups, after obtaining written consent to receive methotrexate 15 mg every Friday and folic acid daily except Fridays or hydroxychloroquine twice a day. For 12 weeks. The patients are clinically evaluated every 4 weeks in terms of the severity of localized scleroderma according to extent of involvement, thickness and flexibility at the start of the trial and weeks 4, 8 and 12 during the intervention, then every 4 weeks up to 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110057712N2**

Registration date: **2011-10-22, 1390/07/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-22, 1390/07/30

Registrant information

Name

Hamideh Azimi

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 41 1541 2120

Email address

azimih@tbzmed.com

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences and Health Services

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hydroxychloroquine with methotrexate in the treatment of patients with localized scleroderma

Public title

Comparison of hydroxychloroquine with methotrexate in the treatment of patients with localized scleroderma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of morphea without any signs of systemic involvement, evidence of active and expanding lesions (evidence of the spreading lesions, the appearance of new lesions or clinical signs of inflammation include erythema and warmth over the past 3 months), morphea confirmed with a histological samples from all patients before treatment, any systemic treatment with effect on morphea had to be discontinued for at least 4 weeks and topical treatments for at least 2 weeks prior to the study, Exclusion criteria: Acute or chronic infection, pregnancy or childbearing potential without an acceptable method to prevent, Liver disease

or elevated liver enzyme levels more than twice the normal, creatinine level of more than 130 mmol, known pulmonary disease, leukocyte count less than 3500 or platelet count less than 150000, active peptic ulcer or neoplasm, insulin-dependent diabetes mellitus, Use of other anti-folate drugs such as sulfonamides, and allopurinol and Probenesid, Presence of Lupus or Mixed connective tissue disease (MCTD), Contraindication of Ophthalmology to start hydroxychloroquine

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences and Health Services

Street address

Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz

City

Tabriz

Postal code**Approval date**

2011-06-29, 1390/04/08

Ethics committee reference number

5/4/2799

Health conditions studied**1****Description of health condition studied**

localized scleroderma

ICD-10 code

L94.0

ICD-10 code description

localized scleroderma(morpea)

Primary outcomes**1****Description**

improvement of clinical lesion

Timepoint

every 4 weeks

Method of measurement

MSS

Secondary outcomes**1****Description**

improvement of induration

Timepoint

every 4 week

Method of measurement

VAS(visual analogue scale)

2**Description**

improvement of pruritus

Timepoint

every 4 weeks

Method of measurement

VAS(visual analogue scale)

Intervention groups**1****Description**

Group A: oral methotrexate 15 mg Fridays and oral folic acid daily except Fridays for 12 weeks

Category

Treatment - Drugs

2**Description**

Group B: oral hydroxychloroquine 200 mg twice a day, for 12 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Dermatology- Sina Hospital- Tabriz

Full name of responsible person

Maryam Nasimi
Street address
Sina Hospital- Azadi Avenue-Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences and Health Services
Full name of responsible person
Dr Meshkini
Street address
Tabriz University of Medical Sciences and Health Services- Daneshghah Avenue- Tabriz
City
Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences and Health Services

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

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Person responsible for updating data

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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