

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Study of methotrexate with phototherapy on vitiligo patients in comparison with phototherapy alone.

#### Protocol summary

##### Study aim

Determination of oral methotrexate and phototherapy effect on vitiligo in comparison with phototherapy alone.

##### Design

Two arm parallel group randomized trial. Double blinded

##### Settings and conduct

The vitiligo patents of Razi hospital who were candidate for phototherapy were randomly divided in two groups. One group of patients received placebo with phototherapy for three times a week another group of patents received methotrexate and phototherapy. None of patients and researchers know about allocation.

##### Participants/Inclusion and exclusion criteria

Older than 18 y/o Patients who are candidate for phototherapy. Vitiligo disease activity more than one. Patients who don't have receive immunosuppressive treatment in the six past month.

##### Intervention groups

Patients were divided into two groups. control group received placebo and phototherapy three times a week. Phototherapy was done using 12 lamps emitting ultraviolet beam with wavelengths between 310 -315 nanometers. another group of patients receive 12.5 milligrams methotrexate weekly and phototherapy three times a week. UV eye glasses were used to protect eyes. Intervention group received phototherapy three times a week and 12.5 mg methotrexate weekly. Patients consume Five 2.5 mg methotrexate tablets on Fridays and one acid folic tablet on sundays.

##### Main outcome variables

Treatment Systemic disease Vitiligo Area Scoring Index  
Vitiligo Disease Activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221013056158N1**

Registration date: **2022-12-11, 1401/09/20**

Registration timing: **retrospective**

Last update: **2022-12-11, 1401/09/20**

Update count: **0**

##### Registration date

2022-12-11, 1401/09/20

##### Registrant information

###### Name

Zahra Sadat Seyedhoseini

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3650 1975

###### Email address

hoseini9020@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-21, 1400/01/01

##### Expected recruitment end date

2023-03-20, 1401/12/29

##### Actual recruitment start date

2021-03-21, 1400/01/01

##### Actual recruitment end date

2022-03-21, 1401/01/01

##### Trial completion date

2022-03-21, 1401/01/01

##### Scientific title

Study of methotrexate with phototherapy on vitiligo patients in comparison with phototherapy alone.

##### Public title

Study of combined methotrexate and phototherapy in vitiligo.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Known case of vitiligo No systemic or local immunosuppressive treatment in past 6 months Vitiligo disease activity more than one Candidates for phototherapy

### Exclusion criteria:

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **42**

Actual sample size reached: **42**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization was used in this study. In this method simple randomization models like tossing a coin, using randomized number tables or computerized methods of randomization is used. In this method each case is allocated in one group (control or intervention) by tossing a coin for example. Some advantages of this method are unpredictability of treatment used for each case. Implementing of this method is simple. Randomization unit of this study is each case.

Randomizer software was used for randomization. This software gives us the ability to choose a desired method of randomization among several others. Randomization sequence was created using randomizer software. The sequence was created asking the software to divide 42 cases into two groups of 21 equally. The software allocated each case to control or intervention group randomly. Central allocation concealment was used in this study. In this method randomization sequence is within a central group other than researchers. Researchers make contact to the central group in order to ask next case allocated group according to the sequence.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The researcher did not know which group got methotrexate and which group got placebo. Patients did not know what kind of treatment they received. Placebo and methotrexate were given to patients by third person.

## Placebo

Used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Tehran, Vahdat Eslami Ave., Razi hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1199663911

#### Approval date

2022-02-16, 1400/11/27

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1358

## Health conditions studied

### 1

#### Description of health condition studied

Vitiligo

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Severity of vitiligo disease

#### Timepoint

Before treatment, after 2 months, 4 months and 6 months of treatment.

#### Method of measurement

Vitiligo Area Scoring Index

### 2

#### Description

Vitiligo activity

#### Timepoint

Before treatment then after 2 months, 4 months and 6 months of treatment.

#### Method of measurement

Vitiligo Disease Activity Scorings

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Vitiligo patients in this group received phototherapy twice a week and oral methotrexate 12/5 milligrams in a week.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Vitiligo patients in this group received phototherapy twice a week and placebo.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi hospital

##### Full name of responsible person

Zahrasadat Seyedhoseini

##### Street address

Vahdat eslami Ave., Razi hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1199663911

##### Phone

+98 21 5563 0553

##### Email

razihospital@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Akbar Fotuhi

##### Street address

Keshavarz Blv., 16 Azar Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417613151

##### Phone

+98 21 81631

##### Email

tumspr@tums.ac.ir

#### 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

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

### 2

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Akbar Fotuhi

##### Street address

Keshavarz Blv., 16 Azar Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417613151

##### Phone

+98 21 81631

##### Email

tumspr@tums.ac.ir

#### 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

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

**Full name of responsible person**

Zahrasadat Seyedhoseini

**Position**

Resident of dermatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Tehran, Razi Ave., Razi hospital.

**City**

Tehran

**Province**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5560 9952

**Email**

hoseini9020@yahoo.com

**Position**

Resident of dermatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No. 57, Ekhtiyariyeh Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1945853547

**Phone**

+98 31 3650 1975

**Fax****Email**

hoseini9020@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Sadat Seyedhoseini

**Position**

Resident of dermatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No. 57, Ekhtiyariyeh Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1945853547

**Phone**

+98 31 3650 1975

**Fax****Email**

hoseini9020@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Sadat Seyedhoseini

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Individual data of cases will be publish. Variables include age, sex, past medical history, received treatment.

**When the data will become available and for how long**

6 months after publish.

**To whom data/document is available**

Researchers of scientific centers and universities.

**Under which criteria data/document could be used**

University professor and researchers can have access to data for research purposes. Systematic review analyses can be performed on the data.

**From where data/document is obtainable**

Researchers can ask to receive data through email address hoseini9020@yahoo.com.

**What processes are involved for a request to access data/document**

Researchers who want to receive data must send his or her scientific resume. After assessment we will reply in one week.

**Comments**