

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Evaluation of the additional effects of two different methods needling (far needling and near needling) for treatment of vitiligo with PUVA

#### Protocol summary

##### Study aim

Evaluation of the additional effects of two different methods needling (far needling and near needling) for treatment of vitiligo with PUVA and comparison far and near needling together

##### Design

This clinical trial with control group and parallel unblind randomised group had done on 8 patient with vitiligo

##### Settings and conduct

This study is a Clinical Trial. The study populations are patients referred to dermatology clinic of Jmam Reza Hospital of Mashhad University of medical sciences. 8 patients with 88 patches of leukoderma in upper limb selected. For 16 patches PUVA (group 1) and for 36 patches PUVA+NEAR NEEDLING (group 2) and for 36 patches PUVA+FAR NEEDLING (group 3) for 3 months (PUVA 3 times weekly and NEEDLING every other week) were done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 12 years, resistance to conventional treatments, indications for PUVA therapy, presence of at least 4 depigmented patches, in both right and left sides of the body, not having a new lesion in the recent 6 months, having consented to participate in the study. Exclusion criteria: hemorrhagic disorders, contraindication for PUVA, patients with positive Koebner phenomenon.

##### Intervention groups

Control group: PUVA alone Intervention group  
1: PUVA+NEAR NEEDLING Intervention group  
2: PUVA+FAR NEEDLING

##### Main outcome variables

Lesion pigmentation change

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140211016554N3**

Registration date: **2019-02-26, 1397/12/07**

Registration timing: **retrospective**

Last update: **2019-02-26, 1397/12/07**

Update count: **0**

##### Registration date

2019-02-26, 1397/12/07

##### Registrant information

###### Name

Vahid Mashayekhi-Goyonlo

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3802 2490

###### Email address

mashayekhiv@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2013-09-23, 1392/07/01

##### Expected recruitment end date

2014-09-23, 1393/07/01

##### Actual recruitment start date

2013-09-23, 1392/07/01

##### Actual recruitment end date

2014-09-23, 1393/07/01

##### Trial completion date

2014-12-14, 1393/09/23

##### Scientific title

Evaluation of the additional effects of two different methods needling (far needling and near needling) for treatment of vitiligo with PUVA

## Public title

Evaluation of the additional effects of two different methods needling (far needling and near needling) for treatment of vitiligo with PUVA

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 12 years Resistance to conventional treatments and indications for PUVA therapy Presence of at least 4 depigmented patches,in both right and left sides of the body Not having a new lesion in the recent 6 months Having consented to participate in the study

### Exclusion criteria:

Hemorrhagic disorders Contraindication for PUVA Patients with positive Koebner phenomenon

## Age

From **12 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **8**

Actual sample size reached: **8**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study simple randomisation had done by computer in order to use random numbers categories

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177899191

## Approval date

2013-06-22, 1392/04/01

## Ethics committee reference number

IR.MUMS.REC.1392.96

## Health conditions studied

### 1

#### Description of health condition studied

Vitiligo

#### ICD-10 code

L80

#### ICD-10 code description

Vitiligo

## Primary outcomes

### 1

#### Description

Lesion pigmentation change

#### Timepoint

After 3 months

#### Method of measurement

Phototherapy

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: PUVA alone.PUVA was done three times a weak for three months

#### Category

Treatment - Other

### 2

#### Description

Intervention group: PUVA+NEAR NEEDLING.Needling was performed every other weak for three months.In this method a 30 gage needle was entered gently from the pigmented lesion margin to the center

#### Category

Treatment - Surgery

### 3

#### Description

Intervention group: PUVA+FAR NEEDLING.In this method a needle was inserted and moved through the hair follicular crater then the needle was expelled and gently inserted in the leukodermal zone

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ghaem hospital

**Full name of responsible person**

Naeimeh Organji

**Street address**

Ghaem hospital, Ahmad Abad Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3801 2493

**Email**

organjin@yahoo.com

### 2

#### Recruitment center

**Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Vahid Mashayekhi

**Street address**

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 5442

**Email**

mashayekhiv@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3841 2081

**Email**

ramresearch@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahid Mashayekhi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 5442

**Email**

mashayekhiv@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahid Mashayekhi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 5442

**Email**

mashayekhiv@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Naeimeh Organji

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Ghaem hospital, Ahmad Abad Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3801 2493

**Email**

organjin@yahoo.com

**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**

Undecided - It is not yet known if there will be 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**

Not applicable

**Data Dictionary**

Not applicable

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

All data can be shared after patients are made unidentifiable

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

Data can be accessible 6 months after results are published.

**To whom data/document is available**

Data will be available for researchers in universities and other scientific institutes.

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

En Carrying out analysis on data is permitted

**From where data/document is obtainable**

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

**Comments**