

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 Jmami 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 week for three months

Category

Treatment - Other

2

Description

Intervention group: PUVA+NEAR NEEDLING. Needling was performed every other week for three months. In this method a 30 gauge 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

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Postal code

9176699199

Phone

+98 51 3801 2493

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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

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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

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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

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Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

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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

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Person responsible for updating data

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Full name of responsible person

Naeimeh Organji

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resident

Latest degree

Medical doctor

Other areas of specialty/work

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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