Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 refereed to dermatology clinic of]mam 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 Intervension group 1:PUVA+NEAR NEEDLING Intervension 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)

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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
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9176699199
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2

Recruitment center

Name of recruitment center
Imam Reza hospital
Full name of responsible person
Vahid Mashayekhi
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Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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