Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of narrow band UVB with needling versus narrow band UVB alone on the treatment of vitiligo: a single blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of narrow band UVB with needling versus narrow band UVB alone on the treatment of vitiligo. Design: A single blinded randomized clinical trial. Setting and conduct: All eligible patients with vitiligo who will refer to clinic of Farshchian Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) age of older than of years; (b) having bilateral symmetrical vitiligo lesions on upper or lower limbs, face, or trunk; (c) the vitiligo is either stable or progressive; (d) at least 10% of the body surface is affected by the disease. Exclusion criteria: (a) being immunodeficient; (b) being spontaneous repigmentation; (c) having any contraindications for phototherapy. Intervention: Needling the margin of the vitiligo lesion toward the center once a week before phototherapy for three months plus phototherapy with NB-UVB once a week for three months. Control: Phototherapy with NB-UVB alone once a week for three months Primary outcome: Repigmentation of the lesion based on VASI criteria in the sixth and twelfth weeks. Secondary outcome: Evaluation of probable superficial burn through clinical observation weekly before phototherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402169014N24**
Registration date: **2014-02-22, 1392/12/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-22, 1392/12/03

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of narrow band UVB with needling versus narrow band UVB alone on the treatment of vitiligo: a single blinded randomized clinical trial

Public title

Effect of narrow band UVB with needling versus narrow band UVB alone on the treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of older than of years; (b) having bilateral symmetrical vitiligo lesions on upper or

lower limbs, face, or trunk; (c) the vitiligo is either stable or progressive; (d) at least 10% of the body surface is affected by the disease. Exclusion criteria: (a) being immunodeficient; (b) being spontaneous repigmentation; (c) having any contraindications for phototherapy.

Age
From **7 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **29**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: Two symmetrical lesions on either side of each patient are selected, one as intervention and the other as control. Thus, each patient will be compared with oneself. Blinding: Photos will be taken from the lesions in the sixth and twelfth weeks. Then the photos will be evaluated and compared with each other by a physician who is not aware of the intervention. Thus, the study will be single blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2012-06-26, 1391/04/06

Ethics committee reference number
D/P/16/35/9/1115

Health conditions studied

1

Description of health condition studied
Vitiligo

ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Repigmentation of the lesion

Timepoint
in the sixth and twelfth weeks

Method of measurement
based on VASI criteria

Secondary outcomes

1

Description
Evaluation of probable superficial burn

Timepoint
weekly before phototherapy

Method of measurement
through clinical observation

Intervention groups

1

Description
Needling the margin of the vitiligo lesion toward the center once a week before phototherapy for three months plus phototherapy with NB-UVB once a week for three months

Category
Treatment - Drugs

2

Description
Phototherapy with NB-UVB alone once a week for three months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Hospital

Full name of responsible person

Dr Amaneh Yazdanfar
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
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
Name of organization / entity
Farshchian Hospital,
Full name of responsible person
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Web page address

Person responsible for updating data

Contact

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