

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

Jalal Poorolajal

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
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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

Dr Mayam Rasouli Mohit

Position

Resident of Dermatology

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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