

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

City
Hamadan

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

Other areas of specialty/work

Street address
Farshchian Hospital, Mirzadeh Eshghi Ave

City
Hamadan
Postal code
Phone
00
Fax
Email
rasouli27@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Farshchian Hospital

Full name of responsible person
Dr Amaneh Yazdanfar

Position
Dermatologist

Other areas of specialty/work

Street address
Farshchian Hospital, Mirzadeh Eshghi Ave

City
Hamadan

Postal code

Phone
+98 918 111 1070

Fax

Email
yazdanfar@usmsha.ac.ir

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