Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of narrow band UVB phototherapy plus betamethasone ointment versus narrow band UVB phototherapy plus placebo ointment on the treatment of vitiligo: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of narrow band UVB phototherapy plus betamethasone ointment versus narrow band UVB phototherapy plus placebo ointment on the treatment of vitiligo. Design: A double 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 7 years or older; (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: Narrow band UVB phototherapy thrice a week plus betamethasone ointment twice a day for three months. Control: Narrow band UVB phototherapy thrice a week plus placebo (eucerin) ointment twice a day 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: **IRCT201402269014N26**
Registration date: **2014-03-09, 1392/12/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-03-09, 1392/12/18

Registrant information

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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

2012-05-21, 1391/03/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of narrow band UVB phototherapy plus betamethasone ointment versus narrow band UVB phototherapy plus placebo ointment on the treatment of vitiligo: a double blinded randomized clinical trial

Public title

Effect of narrow band UVB phototherapy plus betamethasone ointment versus narrow band UVB phototherapy plus placebo ointment on the treatment of

vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 7 years or older; (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 **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: Two symmetrical lesions on either side of each patient are randomly selected, one as intervention and the other as control. Thus, each patient will be compared with oneself. Blinding: The patients will receive ointment with the same shape but different content. Thus, they will not aware of the intervention. The 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 design of the study will be double 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

2012-05-16, 1391/02/27

Ethics committee reference number

D/P/16/35/9/626

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

at 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

Narrow band UVB phototherapy thrice a week plus betamethasone ointment twice a day for three months.

Category

Treatment - Drugs

2

Description

Narrow band UVB phototherapy thrice a week plus placebo (eucerin) ointment twice a day for three months.

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Dr Azam Dalirad
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Farshchian Hospital, Mirzadeh Eshghi Ave
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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
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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

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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