

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of narrow band UVB in combination with 0.1% topical Tacrolimus versus narrow band UVB alone on treatment of patients with vitiligo: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of narrow band UVB in combination with 0.1% topical Tacrolimus versus narrow band UVB alone on treatment of vitiligo. **Design:** A double blind randomized clinical trial. **Setting and conduct:** The eligible patients with vitiligo who will refer to Farshchian Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** presence of bilateral symmetrical vitiligo lesions on upper and lower limbs, face or trunk; fixed or progressive disease process; involvement of at least 10 percent body surface. **Exclusion criteria:** using topical treatments in the past one month; immunodeficiency; any contraindication of phototherapy. **Intervention group:** narrow band UVB at a dose of 0.5 to 1 j/cm² plus 0.1% Tacrolimus topical ointment twice a day for 3 months. **Control group:** narrow band UVB at a dose of 0.5 to 1 j/cm² plus Eucerin (placebo) topical ointment twice a day for 3 months. **Primary outcome:** Measuring vitiligo score using VASI scoring scale before intervention and 1.5 and 3 months after intervention. **Secondary outcome:** Assessing local adverse events (erythema and inflammation) 1.5 and 3 months after intervention through physical examination. **Randomization:** Each patients will be his/her own control. For this purpose, the lesions of one side of the body will be randomly treated with combination therapy and the other side will be treated with placebo. **Blinding:** Patients will be unaware of the type of topical ointment. The physician who will examine the lesions will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606239014N103**

Registration date: **2016-07-01, 1395/04/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-01, 1395/04/11

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

2016-07-10, 1395/04/20

Expected recruitment end date

2017-07-11, 1396/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of narrow band UVB in combination with 0.1% topical Tacrolimus versus narrow band UVB alone on treatment of patients with vitiligo: a double blind randomized clinical trial

Public title

Effect of narrow band UVB in combination with 0.1% topical Tacrolimus versus narrow band UVB alone on treatment of patients with vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of bilateral symmetrical vitiligo lesions on upper and lower limbs, face or trunk; fixed or progressive disease process; involvement of at least 10 percent body surface. Exclusion criteria: using topical treatments in the past one month; immunodeficiency; any contraindication of phototherapy.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: Each patients will be his/her own control. For this purpose, the lesions of one side of the body will be randomly treated with combination therapy and the other side will be treated with placebo. Blinding: Patients will be unaware of the type of topical ointment. The physician who will examine the lesions will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-05-15, 1395/02/26

Ethics committee reference number

IR.UMSHA.REC.1395.72

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Measuring vitiligo score

Timepoint

before intervention and 1.5 and 3 months after intervention

Method of measurement

using VASI scoring scale

Secondary outcomes

1

Description

Assessing local adverse events (erythema and inflammation)

Timepoint

1.5 and 3 months after intervention

Method of measurement

through physical examination

Intervention groups

1

Description

narrow band UVB at a dose of 0.5 to 1 j/cm² plus 0.1% Tacrolimus topical ointment twice a day for 3 months

Category

Treatment - Drugs

2

Description

narrow band UVB at a dose of 0.5 to 1 j/cm² plus Eucerin (placebo) topical ointment twice a day for 3 months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farshchian Hospital

Full name of responsible person

Dr Bahareh Ebrahimi

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

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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

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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 Bahareh Ebrahimi

Position

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Web page address**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