Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
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
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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
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Person responsible for updating data

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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