

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

##### 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

2012-05-21, 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

**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 Azam Dalirad

**Position**

Resident of Dermatology

#### Other areas of specialty/work

**Street address**

Farshchian Hospital, Mirzadeh Eshghi Ave

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**Phone**

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a.delirrad@gmail.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**

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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*