

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effectiveness of vitamin D compared with placebo in vitiligo patients treated with Narrow Band UVB: A randomized control trial

Protocol summary

Summary

The purpose of this study is determination the effectiveness of vitamin D compared to placebo in vitiligo patients treated with Narrow Band UVB (NBUVB) in a PILOT, randomized, double-blind, single-center study. Inclusion criteria: patients with generalized Vitiligo or skin involvement more than or equal to five percent of the body surface. Exclusion criteria: patients with hemodialysis and renal failure, age less than 6 years, phototherapy sessions of less than 2 times a week. Randomization will be performed using the blocks of size 6, through block randomization method. After checking basic parameters like Ca, BUN, Cr, 25-OH VIT D, patients will be treated with placebo or vitamin D, 50000 units, orally, once every two weeks for two months. Ca, BUN, Cr and 25-OH VIT D will be measured again at 10th week after treatment. Patients will be visited monthly and photography will be done at the end of the second month. Interventions: Initially, all patients will be treated by NBUVB at the radiation dose of 0.3 J/CM², twice a week. The dose will be increased by 20% per visit until skin burning or pain will occur. When symptomatic erythema will occur, phototherapy will be stopped until the lesions get healed. Phototherapy will be done twice a week up to 20 weeks. Patients will be followed up for 2 months for to evaluate relapse and treatment outcomes. Patients will be examined at the beginning and at the end of the treatment course and VASI (Vitiligo area severity index) will be calculated in order to assess the extent of their skin involvement.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017031133014N1**

Registration date: **2017-09-06, 1396/06/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-06, 1396/06/15

Registrant information

Name

Zahraalsadat Mousavi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2245 6080

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of vitamin D compared with placebo in vitiligo patients treated with Narrow Band UVB: A randomized control trial

Public title

The effect of vitamin D in vitiligo patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with generalized vitiligo or skin lesions equal or more than five percent of the body surface. Exclusion criteria: patients with hemodialysis and renal failure; receiving thiazide diuretics, lithium utilization; get systemic treatment in the last month; increasing serum leading to drug toxicity; age under 6 years old; phototherapy sessions less than 2 times a week.

Age

From **6 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization will be performed through block randomization method with the blocks of 6. In this method, the randomization will be done until the third person will be randomly assigned to a group, after which the individuals will be allocated to the other group automatically until the 6th blocks will be completed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Golestan street, Shahre Daneshgahi, Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2016-12-27, 1395/10/07

Ethics committee reference number

IR.AJUMS.REC.1395.756

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Changes in the extent of skin involvement

Timepoint

Every 2 months until 4 months

Method of measurement

Based on Vitiligo Area Scoring Index (VASI) Score. In this method body is divided into five separate regions: the hands, upper extremities, trunk, lower extremities and feet. The face and neck areas are assessed separately. One hand unit of the patient (the palm plus the volar surface of the digits) is used as a guide to estimate the baseline percentage of vitiligo involvement of each body region. For each body region, VASI is determined as the product of the vitiligo area in hand units (set at 1% per unit) and the pattern of depigmentation within each hand-unit-measured patch (possible values of 10, 25, 50, 75, 90 or 100%, which are illustrated with a descriptive atlas of patient photographs). VASI, applied to the whole body, will be calculated using the following formula, (possible range 0-100): all body sites (hand units) x depigmentation.

Secondary outcomes

1

Description

Serum 25-hydroxyvitamin D level

Timepoint

At the beginning and at the 11th week of the study

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: Pearl VIT D 50000 unit, Orally, on pearl every 2 weeks, for 2 months Plus Narrow Band UVB, 0.3 J / CM2.

Category

Treatment - Drugs

2

Description

Control group: Placebo, Orally, Every 2 weeks a number for 2 months Plus Narrow Band UVB, 0.3 J / CM2.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Phototherapy Clinic, Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Dr Zahra ALSadat Mousavi

Street address

Skin Ward, Imam Khomeini Hospital, 24 Metry Street, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Behzad Sharif Makhmalzadeh

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Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Golestan street, Shahre Daneshgahi, Ahvaz

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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, Ahvaz Jundishapur 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

Skin Ward, Ahvaz Imam Khomeini Hospital

Full name of responsible person

Dr Zahra ALSadat Mousavi

Position

Resident of Skin diseases

Other areas of specialty/work

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Person responsible for scientific inquiries

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Skin Ward, Ahvaz Imam Khomeini Hospital

Full name of responsible person

Dr Mohammad Omidian

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Associate Professor

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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