

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of vitamin D injection compared to placebo on disease severity in patients with discoid lupus erythematosus

Protocol summary

Study aim

Determining the relationship between usage of vitamin D and the severity of discoid lupus erythematosus

Design

Clinical trial with control group, with parallel group, double-blind, randomized, phase three on 30 patients. A random number table will be used for randomization.

Settings and conduct

In all individuals who met the inclusion criteria, after obtaining informed consent, the severity of the disease will be determined using the Cutaneous LE Disease Area and Severity Index (CLAS) checklist. Antecubital area will be located. The obtained samples will be measured for vitamin D level by quantitative luminescence method. Half of the subjects will receive oral vitamin D for 3 months in addition to standard treatments, after which the severity of the disease will be re-measured by CLAS criteria. Patient grouping will be blinded for all participants and clinical evaluators.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age with discoid lupus erythematosus (DLE) whose diagnosis of the disease was confirmed based on clinical manifestations and histopathological study of the skin sample sent to the pathology department, will be included in the study; People with systemic lupus disease, Active kidney disease, Hepatitis, Malabsorption syndrome, users of corticosteroids, dietary supplements, and oral contraceptives, people who use anticonvulsants (phenytoin and phenobarbital), people with liver enzymes above 40, Abnormal sensitivity to vitamin D, pregnant people will not be included in the study.

Intervention groups

All eligible students will be randomly divided into two groups. In addition to receiving standard daily treatment, one group will receive 1,000 international units of oral vitamin D daily for 3 months. The other group will receive only standard treatment and placebo.

Main outcome variables

The severity of discoid lupus erythematosus using CLAS criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220506054753N1**

Registration date: **2024-01-31, 1402/11/11**

Registration timing: **retrospective**

Last update: **2024-01-31, 1402/11/11**

Update count: **0**

Registration date

2024-01-31, 1402/11/11

Registrant information

Name

Bahareh Mehramuz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 3901

Email address

mehramuzb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of vitamin D injection compared to placebo on disease severity in patients with discoid lupus erythematosus

Public title

Investigating the effect of vitamin D on discoid lupus erythematosus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged over 18 years Patients with DLE whose initial diagnosis based on clinical manifestations was confirmed during a histopathological study of a skin sample sent to the pathology department Referred to the dermatology clinic of Sina Hospital in Tabriz Providing Informed consent

Exclusion criteria:

Systemic lupus erythematosus Active kidney disease Hepatitis Malabsorption syndrome Corticosteroid, dietary supplements and contraceptives, or anticonvulsants (phenytoin and phenobarbital) users People with liver enzymes over 40 Abnormal sensitivity to vitamin D Pregnant women

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by using a table of individual and single-layer random numbers, which is prepared by computers that arrange numbers randomly. Concealed allocation will be done using a central service that is not aware of the research.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants in this study will receive standard treatment for the disease, and randomly half of the patients will receive vitamin D and half placebo in addition to standard treatment. The participants' clinical caregiver, who monitors and evaluates the severity of the disease, is not aware of the patient receiving or not receiving vitamin D and will be kept blind before and after treatment and during the study process to avoid any prejudice. The appearance of the drug under study

and a similar placebo will be selected.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2022-08-03, 1401/05/12

Ethics committee reference number

IR.TBZMED.REC.1401.384

Health conditions studied**1****Description of health condition studied**

Discoid lupus erythematosus

ICD-10 code

L93.0

ICD-10 code description

Discoid lupus erythematosus

Primary outcomes**1****Description**

The severity of discoid lupus erythematosus using CLAS criteria

Timepoint

Measurements before starting treatment and after 3 months of oral vitamin D treatment

Method of measurement

Cutaneous LE Disease Area and Severity Index (CLAS) criteria

Secondary outcomes

1

Description

Vitamin D levels

Timepoint

Before and after the treatment period 3 months

Method of measurement

Individuals will undergo venous blood draw from the Antecubital area after 14-14 hours of fasting. The obtained samples will be measured by vitamin D level by quantitative luminescence method.

Intervention groups

1

Description

Intervention group: taking oral vitamin D3 1000 tablets once a day for 3 months produced by Abidi factory

Category

Treatment - Drugs

2

Description

Control group: taking placebo once a day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Sina Hospital, Tabriz

Full name of responsible person

Bahareh Mehramuz

Street address

Sina Hospital, Between Montazeri crossroad and Hafez, Azadi Street, Tabriz, Iran

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Mehramuzb@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Sina Hospital, Between Montazeri crossroad and Hafez, Azadi Street, Tabriz, Iran

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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Bahareh Mehramuz

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pathology

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Imam Reza hospital, Golgasht street, Daneshgah street

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Person responsible for scientific

inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To perform meta-analysis

From where data/document is obtainable

Bahareh Mehramuz bmehramuz@yahoo.com

What processes are involved for a request to access data/document

Sending email and explaining the reasons to bmehramuz@yahoo.com

Comments