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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Postal code
5163639888
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+98 41 3541 2101
Email
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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+98 41 3541 2101
Email
info@healthfac.tbzmed.ac.ir
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
Street address
Imam Reza hospital, Golgasht street, Daneshgah street
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Person responsible for scientific

inquiries

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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