

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

A randomized, double-blind controlled study of the efficacy of vitamin D supplementation compared with placebo on treatment of Behcet's disease

Protocol summary

Summary

Objectives: Examining the efficacy of vitamin D supplementation in controlling Behcet's disease activity
Design, setting and conduct: In this study a sample of 50 Behcet's disease patients will be recruited randomly in a double blind placebo controlled study. Behcet's disease will be diagnosed by the International Study Group criteria. The aims of the study will be explained to the patients and written informed consents will be obtained. In order to carry out the randomization process, the Randlist software will be used to enter every patient in the treatment or control groups. Participants: A sample of 50 Behcet's disease patients diagnosed according to the International Study Group criteria Inclusion criteria: 1. Having active Behcet's disease: Iranian Behcet's Disease Dynamic Activity Measure (IBDDAM) of more than 2.5 Exclusion criteria: 1. Consumption of vitamin D supplements in the past 6 months 2. Pregnancy 3. Malabsorption 4. Renal failure 5. Hepatic failure Intervention: The treatment group will receive vitamin D soft gels containing 50000 units of cholecalciferol (D-VITIN, Zahravi) every 2 weeks for 6 months. The control group will receive placebo. The disease activity will be measured by the IBDAAM three times during the study: before the intervention, 3 months after the intervention, and 6 months after the intervention. Main outcome measures: Disease activity measured by the IBDAAM.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212216975N4**
Registration date: **2013-03-20, 1391/12/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-20, 1391/12/30

Registrant information

Name

Alireza Khabbazi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-05, 1392/01/16

Expected recruitment end date

2013-04-05, 1392/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized, double-blind controlled study of the efficacy of vitamin D supplementation compared with placebo on treatment of Behcet's disease

Public title

Vitamin D supplementation for the treatment of Behcet's

disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1. Having active Behcet's disease: Iranian Behcet's Disease Dynamic Activity Measure (IBDDAM) more than 2.5 Exclusion criteria: 1. Consumption of vitamin D supplements in the past 6 months 2. Pregnancy 3. Malabsorption 4. Renal failure 5. Hepatic failure

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In order to eliminate the possibility of any probable bias due to the awareness of the patients and assessing physicians about the type of treatment, we will perform a double blind study. Vitamin D and placebo will be encapsulated so that the patients and assessing physicians will not have any knowledge about the type of the treatment. Randomization will be performed by the Randlist software and every patient will be entered in the treatment or control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tabriz University of Medical Sciences

Street address

Ethic committee, 4th floor, Vice chancellor for research, Faculty of medicine, Tabriz University of Medical Sciences

City

Tabriz

Postal code

5166614766

Approval date

2012-12-08, 1391/09/18

Ethics committee reference number

8305/4/5

Health conditions studied

1

Description of health condition studied

Behcet's disease

ICD-10 code

M35.2

ICD-10 code description

Behçet disease

Primary outcomes

1

Description

Behcet's disease activity

Timepoint

Before intervention, 3 and 6 months after intervention

Method of measurement

Iranian Behcet's Disease Dynamic Activity Measure questionnaire

Secondary outcomes

1

Description

Complications of vitamin D supplementation

Timepoint

3 and 6 months after the intervention

Method of measurement

History and physical examination

Intervention groups

1

Description

The treatment group will receive vitamin D soft gel (D-VITIN, Zahravi) containing 50000 units of cholecalciferol [(3 β ,5Z,7E)-9,10-secocholesta- 5,7,10(19)-trien-3-ol] one soft gel orally after meal every 2 weeks for 6 months.

Category

Treatment - Drugs

2

Description

The control group will receive one soft gel containing placebo orally after meal every 2 weeks for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Research Team, Tabriz University of Medical Sciences

Full name of responsible person

Alireza khabbazi

Street address

Rheumatology Research Team, 4th floor, Emam Reza hospital, University street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Vice chancellor for research, 4th floor, Faculty of Medicine, Tabriz University of Medical Sciences

City

Tabriz

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, Tabriz 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

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Full name of responsible person

Mehrzaad Hajjalilo

Position

Assistant professor of medicine/Rheumatologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor of medicine/Rheumatologist

Other areas of specialty/work

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Web page address

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