

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of oral nanocurcumin on disease activity, expression levels of microRNA and Th17 cells and Treg cells development factors and serum IL-17, IL-10 level in Behcet patients

Protocol summary

Study aim

Effect of oral nanocurcumin on disease activity, expression levels of microRNA and Th17 cells and Treg cells development factors and serum IL-17 level in Behcet patients

Design

Double-blinded clinical trial with control group, with parallel groups, randomized. Patients were randomly assigned into two groups of control (n=18) receiving placebo capsules and treated group (n=18) receiving nanocurcumin capsules

Settings and conduct

In this study, the patients with Behcet's syndrome is studied. These individuals are selected randomly from among referrals to rheumatologist at Tabriz University of Medical Sciences, based on laboratory findings and medical records content. The treatment group will receive 80 mg of nanocurcumin The control group will also receive placebo capsules.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20-60 years Diagnosis of Behcet's disease by rheumatologist Selection of patients based on IBCD (International Criteria for Behcet's Disease), suggests that vascular, eye and joints threatening conflicts indicate severity of disease Exclusion criteria: Using nutritional supplements and antioxidant and alpha-lipoic acid during a month before study; Pregnancy&lactation; History of diabetes and other chronic diseases; history of other autoimmune diseases; Admission rate<70% of supplemental intake; Smoking

Intervention groups

The treatment group will receive 80 mg of nanocurcumin The control group will also receive placebo capsules.

Main outcome variables

In this study, the effect of oral nanocurcumin were investigated on the expression of miRNA326, miRNA 155, miRNA181, the frequency of Treg calls and Th17 cells,

the expression of the RoRyt, Foxp3, the expression of the IL-23 and IL-17, IL-10 , TGF-b , and the secretion levels of these cytokines in patients with Behcet disease compared with the control group.

General information

Reason for update

- Use of corticosteroids during illness is removed from exclusion criteria.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160422027520N12**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **prospective**

Last update: **2021-10-15, 1400/07/23**

Update count: **3**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

Department of Immunology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Country

Iran (Islamic Republic of)

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+98 41 3336 4665

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yousefime@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20
Expected recruitment end date
2019-10-12, 1398/07/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of oral nanocurcumin on disease activity, expression levels of microRNA and Th17 cells and Treg cells development factors and serum IL-17, IL-10 level in Behcet patients

Public title
Effect of oral nanocurcumin in patients with Behcet's disease.

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria:

Willingness to cooperate Age range 20 to 60 years
Diagnosis of Behcet's disease by rheumatologist

Exclusion criteria:
Use of nutritional supplements and antioxidant and alpha-lipoic acid during a month before the study
Pregnancy and lactation History of diabetes and other chronic diseases The history of other autoimmune diseases Admission rate less than 70% of supplemental intake Smoking

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
From among the patients who volunteer to participate in the study, 36 individuals will be selected by simple randomization. Randomization method: Blocking
Randomization unit: individual stratification: age and sex
Randomization tool: Random allocation software Method of random sequence generation: Random allocation software Allocation concealment: The generated random sequence will be kept in a protected location and administered by an independent party who is not involved in the trial throughout the study. Due to proper allocation concealment, trial investigators and participants will be unaware of upcoming allocations.

Blinding (investigator's opinion)
Double blinded

Blinding description

This is a double blind study in which the researcher and patients who participate in study will be blinded to the group assignments. The patients will receive the supplements by another person who is not involved in doing the assessment and chemical analysis. Patients will be informed about the type of supplements (nanocurcumin and placebo) however they will not be aware about the group assignments. Placebo capsules are identical to nanocurcumin supplements in shape and color and size.

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

GOLGASHT, University Avenue, Tabriz University of Medical Sciences, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-04-08, 1398/01/19

Ethics committee reference number

IR.TBZMED.REC.1398.037

Health conditions studied

1

Description of health condition studied

Behcet's disease

ICD-10 code

M35.2

ICD-10 code description

Behcet's disease

Primary outcomes

1

Description

The expression of miRNAs

Timepoint

Before and after intervention

Method of measurement

QRT-PCR

2**Description**

Frequency of Th17 cells

Timepoint

Before and after intervention

Method of measurement

Flow cytometry

3**Description**The expression of the RoR γ **Timepoint**

Before and after intervention

Method of measurement

QRT-PCR

4**Description**

IL-23 and IL-17 cytokine gene expression

Timepoint

Before and after intervention

Method of measurement

QRT-PCR

5**Description**

The level of IL-23 and IL-17 cytokine secretion

Timepoint

Before and after intervention

Method of measurement

Elisa

6**Description**

Frequency of Treg cells

Timepoint

Before and after intervention

Method of measurement

Flow cytometry

7**Description**

The expression of the Foxp3

Timepoint

Before and after intervention

Method of measurement

QRT-PCR

8**Description**

TGF-b and IL-10 cytokine gene expression

Timepoint

Before and after intervention

Method of measurement

QRT-PCR

9**Description**

The level of TGF-b and IL-10 cytokine secretion

Timepoint

Before and after intervention

Method of measurement

Elisa

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: nanocurcumin Patients in intervention group will take one 80 mg nanocurcumin capsule (produced by Exir Nanosina pharmaceutical company) with their lunch meal per day over a period of 2 months.

Category

Treatment - Other

2**Description**

Control group: Placebo Patients in control group will take one placebo capsule (produced by Exir Nanosina pharmaceutical company) with their lunch meal per day over a period of 2 months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital, Tabriz

Full name of responsible person

Mehdi Yousefi, Ph.D Of Medical Immunology

Street address

Imam Reza Hospital, Golgasht Avenue, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Connective Tissue Diseases Research Center

Full name of responsible person

Dr. Alireza Khabbazi

Street address

4rd floor, Connective Tissue Diseases Research Center, Imam Reza Hospital, Golgasht St, Tabriz, Iran

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dr_khabbazi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Connective Tissue Diseases Research Center

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

Department of Immunology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Full name of responsible person

Mehdi Yousefi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable