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 RoRγt، 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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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 scienece

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 RoRγ
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
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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
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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
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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