

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effects of oral nanocurcumin on expression levels of microRNA and Th17 cells development factors in ankylosing spondylitis patients

#### Protocol summary

##### Study aim

To evaluate the effects of oral nanocurcumin in levels of micro-RNA expression and Th17 cell development factors in patients with ankylosing spondylitis

##### Design

Clinical trials with control group, with parallel groups, randomized. Patients were randomly assigned into two groups of control (n = 12) receiving placebo capsules and treated group (n = 12) receiving nanocurcumin capsules

##### Settings and conduct

In this study, patients with ankylosing spondylitis is studied. These individuals are selected randomly from among referrals to neurologist at Tabriz University of Medical Sciences, based on laboratory findings and medical records content. The treatment group received 80 mg of nanocurcumin The control group also received placebo capsules.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Willingness to cooperate; ranging in age 28 to 51 years; diagnosis of ankylosing spondylitis by rheumatologist; patients with a BASDAI > 4 as having active disease; disease duration 5-8 years. Exclusion Criteria: Use of nutritional supplements and antioxidant and immunosuppressive drugs alpha-lipoic acid a month before the study; pregnancy and lactation; history of diabetes and other chronic diseases; history of other autoimmune diseases.

##### Intervention groups

Intervention group: nanocurcumin Patients in intervention group took nanocurcumin capsules on a daily basis over a period of 4 months. Control group: Placebo The control capsule took on a daily basis over a period of 4 months.

##### Main outcome variables

In this study, the effect of oral nanocurcumin were investigated on the expression of miRNA326, the frequency of Th17 cells, the expression of the RoRyt the expression of the IL-17, and the secretion levels of this

cytokine in patients with ankylosing spondylitis compared with the control group.

#### General information

##### Reason for update

##### Acronym

AS

##### IRCT registration information

IRCT registration number: **IRCT2017052927520N7**

Registration date: **2017-06-13, 1396/03/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-08, 1398/06/17**

Update count: **1**

##### Registration date

2017-06-13, 1396/03/23

##### 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)

##### Phone

+98 41 3336 4665

##### Email address

yousefime@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2017-04-20, 1396/01/31

##### Expected recruitment end date

2017-12-29, 1396/10/08

**Actual recruitment start date**

2017-04-29, 1396/02/09

**Actual recruitment end date**

2017-11-07, 1396/08/16

**Trial completion date**

2018-01-18, 1396/10/28

**Scientific title**

The effects of oral nanocurcumin on expression levels of microRNA and Th17 cells development factors in ankylosing spondylitis patients

**Public title**

Oral nanocurcumin and treatment of ankylosing spondylitis

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to cooperate; ranging in age 28 to 51 years diagnosis of ankylosing spondylitis by rheumatologist patients with a BASDAI > 4 as having active disease disease duration 5-8 years

**Exclusion criteria:**

Use of nutritional supplements and antioxidant and immunosuppressive drugs alpha-lipoic acid a month before the study pregnancy and lactation history of diabetes and other chronic diseases history of other autoimmune diseases acceptance rate of less than 70% of supplements not wanting to continue cooperation.

**Age**

From **28 years** old to **51 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **24**

Actual sample size reached: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization Blocking were used to balance the number of samples assigned to each study groups . The size of all blocks is equal and the blocks included 12 participants in the intervention group, who receive nanocurcumin capsules and 12 participants in the control group who receive placebo capsules.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

1. Participant 2. Outcome assessor

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

CT.gov

**Secondary trial Id**

NCT03140657

**Registration date**

2017-05-04, 1396/02/14

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

Connective Tissue Diseases Research Center

**Street address**

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

**City**

TABRIZ

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2016-08-29, 1395/06/08

**Ethics committee reference number**

IR.TBZMED.REC.1395.599

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

Ankylosing Spondylitis

**ICD-10 code**

M45

**ICD-10 code description**

Ankylosing spondylitis

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

miRNA-326

**Timepoint**

Before interference and four months after interference

**Method of measurement**

Examined the expression levels of miRNA-326 by using Quantitative Real time PCR

**2****Description**

The frequency of Th17 cells

**Timepoint**

Before interference and four months after interference

### Method of measurement

Examined the frequency of Th17 cells by using flow cytometry

### 3

#### Description

Transcription factor: RoRyt

#### Timepoint

Before interference and four months after interference

#### Method of measurement

Examined the expression levels of RoRyt by using Quantitative Real time PCR

### 4

#### Description

Cytokine: IL-17

#### Timepoint

Before interference and four months after interference

#### Method of measurement

Examined the expression levels of IL-17 by using Quantitative Real time PCR

### 5

#### Description

Cytokine: IL-17

#### Timepoint

Before interference and four months after interference

#### Method of measurement

Examined the amount of secreted cytokine IL-17 by using sandwich ELISA method.

## Secondary outcomes

### 1

#### Description

Cellular and molecular changes in the immune system

#### Timepoint

after 4 months

#### Method of measurement

Flow cytometry, ELISA, RT-PCR

## Intervention groups

### 1

#### Description

Supplementation group received nanocurcumin capsules containing 80 mg nanocurcumin once a day for four months

#### Category

Treatment - Drugs

### 2

#### Description

The control group received placebo capsules once a day for four months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital, Tabriz

##### Full name of responsible person

Sanam Dolati

##### Street address

Imam Reza Hospital, Golgasht Avenue, Tabriz Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

##### Phone

+98 41 3336 4665

##### Email

yousefime@tbzmed.ac.ir

## 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

##### City

Tabriz

##### Province

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##### Postal code

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##### Phone

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##### Email

yousefime@tbzmed.ac.ir

#### 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Yousefi

**Position**

Ph.D Of Medical Immunology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sanam Dolati

**Position**

Ph.D student of Immunology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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sanam.dolati@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Yousefi

**Position**

Ph.D Of Medical Immunology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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**Province**

East Azarbaijan

**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**

Not applicable

**Data Dictionary**

Not applicable