

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Connective Tissue Diseases Research Center

Full name of responsible person

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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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Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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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

Not applicable

Data Dictionary

Not applicable