Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The effects of oral nanocurcumin on expression levels of microRNAs and Treg cells and Th17 cells development factors in Multiple Sclerosis patients

Protocol summary

Study aim

To evaluate the effects of oral nanocurcumin, in levels of micro-RNAs expression and Treg and Th17 cell development factors in patients with multiple sclerosis

Design

Clinical trials with control group, with parallel groups, randomized. Patients were randomly assigned into two groups of control (n = 25) receiving placebo capsules and treated group (n = 25) receiving nanocurcumin capsules

Settings and conduct

In this study, patients with multiple sclerosis 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: Ranging in age from 28 to 51 years MS diagnosis by neurologist patients in relapse and remitting EDSS<5/5 Exclusion criteria: History of diabetes and other chronic diseases; History of other autoimmune disease; corticosteroid use during illness; the occurrence of relapses during the study phase

Intervention groups

Intervention group: nanocurcumin Patients in intervention group took nanocurcumin capsules on a daily basis over a period of 6 months. Control group: Placebo The control capsule took on a daily basis over a period of 6 months.

Main outcome variables

In this study, the effect of oral nanocurcumin were investigated on the expression of miRNA326, miRNA 106, miRNA25, 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 multiple sclerosis compared with the control group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042227520N1**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **prospective**

Last update: **2019-09-04, 1398/06/13**
Update count: **1**

Registration date

2016-05-29, 1395/03/09

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

Drug Applied Research Center Tabriz University Of Medical Sciences

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date
2016-06-08, 1395/03/19

Actual recruitment end date
2016-08-10, 1395/05/20

Trial completion date
2017-11-07, 1396/08/16

Scientific title
The effects of oral nanocurcumin on expression levels of microRNAs and Treg cells and Th17 cells development factors in Multiple Sclerosis patients

Public title
The effects of oral nanocurcumin in Multiple Sclerosis patients

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to cooperate; Ranging in age from 28 to 51 years MS diagnosis by neurologist patients in relapse and remitting EDSS<5/5

Exclusion criteria:
Used nutritional supplements and antioxidants and alpha lipoic acid within a month before the study Pregnancy and lactation; History of diabetes and other chronic diseases; History of other autoimmune disease; corticosteroid use during illness; the occurrence of relapses during the study phase; 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: **50**
Actual sample size reached: **41**

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 25 participants in the intervention group, who receive nanocurcumin capsules and 25 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
ClinicalTrials.gov

Secondary trial Id
NCT03150966

Registration date
2017-05-12, 1396/02/22

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences , Golgasht Avenue, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2016-03-07, 1394/12/17

Ethics committee reference number
TBZMED.REC.1394.1177

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
miRNA-106b

Timepoint
Before interference and six months after interference

Method of measurement
Examined the expression levels of miRNA-106b by using Quantitative Real time PCR

2

Description
miRNA-25

Timepoint
Before interference and six months after interference
Method of measurement
Examined the expression levels of miRNA-25 by using Quantitative Real time PCR

3

Description
miRNA-326
Timepoint
Before interference and six months after interference
Method of measurement
Examined the expression levels of miRNA-326 by using Quantitative Real time PCR

4

Description
The frequency of Treg cells
Timepoint
Before interference and six months after interference
Method of measurement
Examined the frequency of Treg cells by using flow cytometry

5

Description
The frequency of Th17 cells
Timepoint
Before interference and six months after interference
Method of measurement
Examined the frequency of Th17 cells by using flow cytometry

6

Description
Transcription factor: Foxp3
Timepoint
Before interference and six months after interference
Method of measurement
Examined the expression levels of Foxp3 by using Quantitative Real time PCR

7

Description
Transcription factor: RoRγt
Timepoint
Before interference and six months after interference
Method of measurement
Examined the expression levels of RoRγt by using Quantitative Real time PCR

8

Description
Cytokine: TGF-β
Timepoint
Before interference and six months after interference
Method of measurement
Examined the expression levels of TGF-β by using Quantitative Real time PCR

9

Description
Cytokine: IL-17
Timepoint
Before interference and six months after interference
Method of measurement
Examined the expression levels of IL-17 by using Quantitative Real time PCR

10

Description
Cytokine: TGF-β
Timepoint
Before interference and six months after interference
Method of measurement
Examined the amount of secreted cytokine TGF-β by using sandwich ELISA method.

11

Description
Cytokine: IL-17
Timepoint
Before interference and six months after interference
Method of measurement
Examined the amount of secreted cytokine IL-17 by using sandwich ELISA method.

Secondary outcomes

empty

Intervention groups

1

Description
The control group received placebo capsules once a day for six months.
Category
Treatment - Drugs

2

Description
Supplementation group received nanocurcumin capsules containing 80 mg nanocurcumin once a day for six months .
Category
Treatment - Drugs

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
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
Drug Applied Research Center
Full name of responsible person
Hossein Babaei
Street address
Drug Applied Research Center, Tabriz University of Medical Sciences, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 4665
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
Drug Applied 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 / Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Tabriz University of Medical Sciences, Golgasht Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 4665
Fax
Email
Yousefime@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
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5166614766
Phone
+98 41 3336 4665
Fax
Email
Yousefime@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Yousefi
Position
Ph.D Of Medical Immunology / Assistant Professor

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Immunology
Street address
Tabriz University of Medical Sciences, Golgasht Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 4665
Fax
Email
Yousefime@tbzmed.ac.ir
Web page address

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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable