Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Clinical trial evaluating the effects of curcumin nanoformula on TH17 and Treg cell-related markers in patients with rheumatoid arthritis and comparing it with placebo

Protocol summary

Study aim

1) Determining and comparing the frequency of TH17 and Treg cell populations in the study groups before and after the intervention 2) Determining and comparing the expression of RORγt, FOXP3, mir-20b, mir-223, Lnc-HOTAIR and Lnc-MEG3 genes in the studied groups before and after the intervention 3) Determining and comparing CRP, ESR and Anti-CCP levels in the study groups before and after the intervention

Design

Thirty female patients with RA who were divided into two intervention groups (curcumin nano-formulation and placebo), three-blind, randomized block classification randomized method, matched in terms of age and body mass index (Frequency matching) To be

Settings and conduct

Background: Rheumatoid arthritis Location: Ali Ibn Abitaleb Hospital in Zahedan Sample: 10cc of blood before and after the intervention Methods: 1- Molecular part: miRNA and total RNA isolated from blood, then cDNA synthesis and finally measuring the expression of the desired genes by real time PCR 2- Cellular section: Flow cytometric examination of TH17 and Treg cells 3- Laboratory analytes: CRP, ESR and Anti-CCP measurements

Participants/Inclusion and exclusion criteria

Female patients between 18-65 years old with rheumatoid arthritis with disease activity rate of 2.8 to 5 selected by rheumatologist Exclusion criteria: heart and infectious diseases, pregnancy and lactation, neurological disorders and patients with creatinine and abnormal liver enzymes

Intervention groups

1- Curcumin nanoformal drug in a period of 3 months in the amount of 40 mg per day 2- Placebo which is given to the control group for 3 months

Main outcome variables

1- Changing the expression of genes considered in the study 2- Changing the percentage of TH17 and Treg cells 3. Changes in laboratory analytes considered by patients: CRP, ESR and Anti-CCP 4- Other than clinical signs and joint pain considered by the patient by a specialist

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220309054225N1**
Registration date: **2022-04-19, 1401/01/30**
Registration timing: **prospective**

Last update: **2022-04-19, 1401/01/30**
Update count: **0**

Registration date

2022-04-19, 1401/01/30

Registrant information

Name

Marzieh Reisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3343 8551

Email address

reisimarzieh2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial evaluating the effects of curcumin nanoformula on TH17 and Treg cell-related markers in patients with rheumatoid arthritis and comparing it with placebo

Public title

The effect of curcumin (a substance extracted from turmeric) on the immune system and clinical signs in patients with rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are women The age range is between 18-65 years Measured by the European American College Rheumatology Criteria (EULAR-ACR) by a rheumatologist Their DAS (disease activity scort28) is between 8.2 and 5, which is assessed by a rheumatologist.

Exclusion criteria:

Refusal to give informed consent Chronic Diseases affecting ESR, CRP levels such as diabetes and heart disease Pregnancy and lactation Nervous disorders Abnormal Creatinine (greater than 1/5) Abnormal liver enzymes (AST-ALT) (3 times normal)

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients into two groups is performed by permutation block stratified randomization method. First, the groups (eligible patients) are frequently matched in terms of age and body mass index. Then, based on the two blocks (consisting of two groups B, A) that are randomly selected from all possible modes of permutations, they are assigned to the desired group. These blocks were created using statistical software R version 4.0.2. Assuming that group A is taking placebo with routine and group B is taking curcumin with routine.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this research, the triple blind study method is used. People who will not be aware of the intervention in this study include: 1- Participants (as we will explain to eligible patients that you have entered a study in which there are two groups of intervention, but they should not fully understand what group they are in, of course, the specialist assures them that this The intervention is made of natural materials and will not have significant side effects) 2- The person in charge of providing drugs and intervention (rheumatologist: in such a way that the interventions are completely identical in appearance so that the doctor does not understand the type of intervention until the end of the study, which examines the consequences and clinical signs with prior notice and Not a personal expectation) 3- Responsible for recording the laboratory results of the study (laboratory expert: in such a way that the blood sample is delivered to the expert with special coding so that he does not understand at all what kind of intervention the sample is using and according to personal request from the study result, the results Do not change) 4- Responsible for data analysis (Statistics Supervisor: As in the case above with the code, the results are announced until the data analysis is done without any personal intervention)

Placebo

Used

Assignment

Parallel

Other design features

in the study, the expression of a number of genes is examined by curcumin intervention, which genes are effective in the balance of immune cells

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Yazd Medical Sciences Campus , Anonymous Martyrs Boulevard , Prof. Hesabi Boulevard , Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

IR.SSU.MEDICINE.REC.1400.400

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis
ICD-10 code
M06.9
ICD-10 code description
Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
Percentage of TH17 cell number
Timepoint
Measurement of TH17 cell count at the beginning of the study (before the intervention) and 3 months after the start of the use of curcumin nano-formulation or placebo
Method of measurement
Flow cytometry method

2

Description
Abundance of Treg cell population (regulatory)
Timepoint
Measurement of Treg cell count at the beginning of the study (before the intervention) and 3 months after the start of the use of curcumin nano-formulation or placebo
Method of measurement
Flow cytometry method

3

Description
gene expression Lnc-HOTAIR (Long non coding)
Timepoint
Evaluation of Lnc-HOTAIR gene expression at the beginning of the study (before intervention) and 3 months after starting the use of curcumin nano-formulation or placebo
Method of measurement
First the primer design, then the cDNA synthesis is measured with special kits and finally with real time PCR.

4

Description
gene expression Lnc-MEG3 (Long non coding)
Timepoint
Evaluation of Lnc-MEG3 gene expression at the beginning of the study (before intervention) and 3 months after starting to use curcumin nano-formulation or placebo
Method of measurement
Measurement before intervention (curcumin or placebo) and 3 months after intervention

5

Description
gene expression mir-20b (micro RNA)
Timepoint
Evaluation of mir-20 gene expression at the beginning of the study (before the intervention) and 3 months after the start of curcumin nano-formulation or placebo
Method of measurement
First the primer design, then the cDNA synthesis is measured with special kits and finally with real time PCR.

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Description
gene expression mir-223 (micro RNA)
Timepoint
Evaluation of mir-223 gene expression at the beginning of the study (before intervention) and 3 months after starting to use curcumin nano-formulation or placebo
Method of measurement
First the primer design, then the cDNA synthesis is measured with special kits and finally with real time PCR.

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Description
gene expression FOXP3
Timepoint
Evaluation of FOXP3 gene expression at the beginning of the study (before intervention) and 3 months after the start of curcumin nano-formulation or placebo
Method of measurement
First the primer design, then the cDNA synthesis is measured with special kits and finally with real time PCR.

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Description
gene expression RORγt
Timepoint
Evaluation of RORγt gene expression at the beginning of the study (before intervention) and 3 months after starting to use curcumin nano-formulation or placebo
Method of measurement
First the primer design, then the cDNA synthesis is measured with special kits and finally with real time PCR.

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Description
Measurement of C-Reactive Protein
Timepoint
Evaluation of CRP gene expression at the beginning of the study (before intervention) and 3 months after the start of curcumin nano-formulation or placebo
Method of measurement
It is measured with a mini neph nephelometer and its scale is milligrams per deciliter

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Description
ESR (erythrocyte sedimentation rate) measurement

Timepoint
Evaluation of ESR gene expression at the beginning of the study (before the intervention) and 3 months after the start of curcumin or placebo nano-formulation
Method of measurement
The ESR rate is performed by the Westergreen method on a scale of millimeters per hour

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Description
Anti-CCP measurement (antibody against cyclic citrulline peptide)
Timepoint
Evaluation of Anti-CCP gene expression at the beginning of the study (before the intervention) and 3 months after the start of curcumin nano-formulation or placebo
Method of measurement
Dedicated kit with ELISA method

Secondary outcomes

1

Description
Disease activity in rheumatoid arthritis patients in the study groups
Timepoint
Before the start of the study and 3 months after taking the nanoformal drug curcumin
Method of measurement
Rheumatology criteria by European American College (EULAR-ACR), disease activity and number of sensitive and swollen joints and other related symptoms are evaluated by a rheumatologist

Intervention groups

1

Description
Intervention group: Curcumin nanoformal drug with the specific name of Sina Curcumin produced by Elixir Nanocina Company, 40 mg capsule daily for a period of 3 months, in the group receiving curcumin along with routine drug
Category
Treatment - Drugs

2

Description
Control group: placebo in a single dose daily for 3 months in the placebo group with routine medicine
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abitaleb Hospital, Zahedan
Full name of responsible person
Mahnaz Sandoghi
Street address
Ali Yen Abitaleb Hospital , Salamat Boulevard , Persian Gulf Highway , Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743111
Phone
+98 913 886 7267
Email
public@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amir Houshang Mehrparvar
Street address
Campus of Shahid Sadoughi University of Medical Sciences , Shahid Dr. Bahonar Square , Yazd
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3726 3733
Email
dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
yazd
Proportion provided by this source
20
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
Yazd University of Medical Sciences
Full name of responsible person
Marzieh Raisi
Position
post graduation
Latest degree
Bachelor
Other areas of specialty/work
post graduation
Street address
No. 2 , first alley , right , 14 Qalanbar St., Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816643181
Phone
+98 54 3343 8551
Email
reisimarzieh2016@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mahdi Atabaki
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Department of Immunology , School of Medicine , Dr. Hesabi Sq., Zahedan Zahedan University of Medical Sciences ,
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
atabaki80@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Marzieh Raisi
Position
postgraduate-student
Latest degree
Bachelor
Other areas of specialty/work
Immunology
Street address
No. 2 , in front of the green space , 14 Qalanbar St. , Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816643181
Phone
+98 54 3343 8551
Email
reisimarzieh2016@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the clinical part of the study is made available to patients after identifying individuals, and other information, including molecular, laboratory, and clinical studies, is provided to academic researchers in detail for further research in This field is helpful .
When the data will become available and for how long
Access to information is approximately 4 to 6 months after the results are published
To whom data/document is available
Data from this study are available to patients, academic researchers, drug companies, and rheumatologists.
Under which criteria data/document could be used
It is explained to patients that after the information obtained from this study is in line with the improvement of clinical conditions, other patients should not be generally recommended to use it because the study is designed with certain criteria and under the supervision of pharmacologists, rheumatologists and immunologists. For academic researchers to obtain more information in this field, for example in their future research can be more maneuverable on the number of samples, the dose of drug use and even design more robust studies using molecular information and methods. Study information may be useful for the manufacturer to improve the quality of the drug.
From where data/document is obtainable
For information about patients, refer to Dr. Mahnaz

Sandoghi, a specialist in rheumatology Address: Ali Ibn Abi Taleb (AS) Hospital - Salamat Boulevard - Persian Gulf Highway Tel: 09151613472 Other information by request by email to Ms. Marzieh Raisi, Master of Immunology reisimarzieh2016@gmail.com

What processes are involved for a request to access data/document

Study information 6 months after the publication of all domestic and foreign articles and receiving complete information from researchers who intend to research in this field, the information will be provided to them at intervals and in accordance with the law of copy paste

Comments