

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 ROR γ t, 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

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Iran (Islamic Republic of)

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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 RORyt

Timepoint

Evaluation of RORyt 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

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
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Full name of responsible person
Marzieh Raisi
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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