Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Study of the effect of oral curcumin on disease development in patients with rheumatoid arthritis

Protocol summary

Study aim
The purpose of this study is, selecting the drugs which can use for the long-term treatment of rheumatoid arthritis while preserving therapeutic effects with fewer complications.

Design
a Phase 3 and double-blind study on 60 patients aged 18 to 72 years, in two therapeutic groups each one contain 30 patients treated with curcumin and placebo tablets, in which patients and researchers do not know which patient gets the placebo and who gets the original drug

Settings and conduct
Patients will be registered at Ghaem Hospital so it is a single central study. Actually the study is conducted at Clinic of Ghaem Hospital and the Rheumatic Disease Research Center of Mashhad University of Medical Sciences. The study is double blind, patients and researchers have no information about whether the drug or placebo is given to the patient. The only one who knows is the analyzer .

Participants/Inclusion and exclusion criteria
The main inclusion criteria are the diagnosis of rheumatism and personal satisfaction, and the main exclusion criteria are effected kidney disease, liver failure and diabetes, as well as having a history of curcumin allergy. pregnancy and Breast feeding

Intervention groups
Mentioned drug (Curcumin Drug) and placebo are given as 80 mg nanomimes (capsules of 80 mg) per day for 3 months were intake by patients.

Main outcome variables
Clinical symptoms and the disease activity before starting treatment based on DAS 28 criteria and beyond.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170812035630N1**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-21, 1396/11/01**
Update count: **0**

Registration date
2018-01-21, 1396/11/01

Registrant information

Name
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Name of organization / entity
Mashhhad University Of Medical Sciences

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Recruitment status
Recruitment complete

Funding source
Mashhad University Of Medical Sciences

Expected recruitment start date
2017-08-23, 1396/06/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of oral curcumin on disease development in patients with rheumatoid arthritis

Public title
Study of the effect of curcumin on rheumatism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed with RA according to eular criteria Personal satisfaction
Exclusion criteria:
Curcumin sensitivity Diabetes Pregnancy
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study randomization method based on closed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients give informed consent, but patients don't know whether they are in placebo group, or the original drug group also researcher don't know whether Patients are members of which group شدی the only aware person is analyzer.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Qureshi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Approval date
2014-10-01, 1393/07/09
Ethics committee reference number
IR,MUMS.REC.1394.303

Health conditions studied

1

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

Primary outcomes

1

Description
Disease activity
Timepoint
Before taking curcumin and 3 months after taking curcumin
Method of measurement
Questionnaire DAS 28 (Disease Activity Square 28)

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group for 3 months, patients treated with curcumin (in the form of nanomissile) are given as 80 mg (80 mg capsules) per day.
Category
Treatment - Drugs

2

Description
In the control group, for 3 months, patients received placebo treatment at a dose of 80 mg (as capsule 80 mg placebo) per day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital Clinic
Full name of responsible person
Afshin Saraf
Street address

Ahmad abad AVE
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Challencellor of Mashhad University of Medical Sciences
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
Vice Challencellor of Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Full name of responsible person
Afshin Saraf
Position
Internal Resident
Latest degree
Specialist
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Person responsible for updating data

Contact
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable