# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

# Evaluation of the Effects of Nanomicellar Curcumin Supplementation on Inflammatory Markers and Quality of Life in Patients with ANCA-Associated Vasculitis: A Randomized Controlled Clinical Trial

## Protocol summary


**Study aim**

To evaluate the efficacy of nano-micellar curcumin supplementation on systemic inflammation and clinical symptoms in patients with ANCA-associated vasculitis.

**Design**

A randomized, double-blind, placebo-controlled clinical trial involving 45 patients with GPA, randomly allocated in a 1:1 ratio to nano-micellar curcumin (n=23) or placebo (n=22) for 3 months, in addition to standard treatment.

**Settings and conduct**

This is a randomized, double-blind, placebo-controlled clinical trial involving 45 patients with mild-to-moderate active granulomatosis with polyangiitis (GPA), conducted at the Rheumatology Clinics of Imam Reza Hospital and Ghaem Hospital in Mashhad, Iran. Participants will be randomly allocated in a 1:1 ratio to receive either nano-micellar curcumin (40 mg twice daily for 3 months) or matching placebo, in addition to standard treatment. The investigational product and placebo will be identical in appearance and coded. Participants, investigators, and outcome assessors will remain blinded to treatment allocation until completion of data analysis.

**Participants/Inclusion and exclusion criteria**

A randomized, double-blind, placebo-controlled clinical trial involving 45 patients with mild-to-moderate active GPA at Imam Reza and Ghaem Hospitals in Mashhad. Participants will be randomly allocated in a 1:1 ratio using blocks of four to receive nano-micellar curcumin 40 mg twice daily for 3 months (n=23) or placebo (n=22).

**Intervention groups**

Intervention group (n=23): Standard treatment + nano-micellar curcumin 40 mg twice daily for 3 months. Control group (n=22): Standard treatment + placebo, one capsule twice daily for 3 months.

**Main outcome variables**

Primary outcome: Serum IL-6 level Secondary outcomes: Prooxidant–antioxidant balance (PAB); disease activity assessed by the BVAS; quality of life assessed using the SF-36 questionnaire; and inflammatory markers, including ESR and CRP


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20191221045837N6**
Registration date: **2026-08-22, 1405/05/31**
Registration timing: **prospective**

Last update: **2026-08-22, 1405/05/31**
Update count: **0**

**Registration date**

2026-08-22, 1405/05/31

**Registrant information**


**Name**

Zinat Heidari

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-09-23, 1405/07/01

**Expected recruitment end date**

2028-09-22, 1407/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the Effects of Nanomicellar Curcumin Supplementation on Inflammatory Markers and Quality of Life in Patients with ANCA-Associated Vasculitis: A Randomized Controlled Clinical Trial

**Public title**

Effect of Nano-Micellar Curcumin on ANCA-Associated Vasculitis

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Confirmed diagnosis of Granulomatosis with Polyangiitis (GPA) based on the ACR/EULAR classification criteria and the 2012 Chapel Hill Consensus Conference nomenclature. Age: Patients aged 18–70 years.Disease activity: Newly diagnosed patients with active mild-to-moderate GPA (BVAS of 2–15) who require standard treatment. Standard treatment will include corticosteroids combined with conventional immunosuppressive agents used for mild-to-moderate disease, including methotrexate, azathioprine, or mycophenolate mofetil, according to the treating rheumatologist’s judgment and the patient’s clinical condition. Informed Consent: Willingness and ability of the patient to participate in the study and provide written informed consent.

**Exclusion criteria:**

Known hypersensitivity or severe adverse reaction to curcumin or any component of the nano-micellar curcumin formulation. Presence of severe pre-existing comorbidities, including cardiovascular insufficiency/disorders requiring anticoagulant therapy; hepatic involvement, defined as elevated liver enzymes (AST or ALT) more than three times the upper limit of normal, evidence of advanced cirrhosis, hepatic failure, or Child–Pugh class B/C; or active malignancy. Pregnancy or breastfeeding at the time of study initiation. Use of curcumin-containing supplements within the previous 3 months. Use of other supplements or medications that substantially affect oxidative stress levels, such as high-dose vitamin E or vitamin C.

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

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

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization Method: A permuted block randomization method will be used to generate the allocation sequence, ensuring equal allocation of participants to the two study groups. The randomization sequence will be generated using the website www.randomization.com

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

To ensure allocation concealment, the investigational drug and placebo will be prepared by the pharmaceutical company in identical packaging with respect to appearance, color, size, and labeling, and will be coded. The group allocation codes will be kept by an individual outside the research team. The investigators, participants, and outcome assessors will remain blinded to the intervention assignment until completion of the data analysis. In the event of a medical emergency, the allocation code for the relevant participant may be unblinded.

**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**

Khorasan Razavi, Mashhad, Azadi Sq, Fcaulty of Pharmacy

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**Postal code**

9177948954

**Approval date**

2026-06-20, 1405/03/30

**Ethics committee reference number**

IR.MUMS.REC.1405.094

## Health conditions studied

### 1

**Description of health condition studied**

Granulomatosis with Polyangiitis (GPA)

**ICD-10 code**
M31.7
**ICD-10 code description**
Microscopic polyangiitis

## Primary outcomes

### 1

**Description**
Serum interleukin-6 (IL-6) level
**Timepoint**
At baseline and 3 months after initiation of curcumin supplementation (end of the study).
**Method of measurement**
ELISA

## Secondary outcomes

### 1

**Description**
Prooxidant–Antioxidant Balance (PAB): PAB will be assessed indirectly based on prooxidant and antioxidant markers. MDA will be measured as a prooxidant marker and TAC as an antioxidant marker.
**Timepoint**
At baseline and 3 months after initiation of curcumin supplementation (end of the study).
**Method of measurement**
Serum MDA will be measured using the TBARS assay, and total antioxidant capacity (TAC) will be assessed using a standard commercial assay kit. PAB will be evaluated based on the MDA and TAC results.

### 2

**Description**
Disease activity assessment using BVAS v3: Disease activity will be assessed using the Birmingham Vasculitis Activity Score (BVAS) version 3.
**Timepoint**
At baseline and 3 months after initiation of curcumin supplementation (end of the study).
**Method of measurement**
BVAS is a disease activity scoring system that assesses active organ involvement based on new or worsening clinical manifestations within the previous 4 weeks. The total score is recorded as the measure of disease activity.

### 3

**Description**
Quality of life assessment
**Timepoint**
At baseline and 3 months after initiation of curcumin supplementation (end of the study).
**Method of measurement**
Health-related quality of life will be assessed using the SF-36 questionnaire, which evaluates eight functional domains. The validity and reliability of the Persian version of the SF-36 have been established in previous studies in Iran.

### 4

**Description**
Inflammatory marker assessment
**Timepoint**
At baseline and 3 months after initiation of curcumin supplementation (end of the study).
**Method of measurement**
CRP will be measured using the ELISA method, and ESR will be measured using the Westergren method at baseline and at month 3.

## Intervention groups

### 1

**Description**
Intervention group: Participants in this group will receive nano-micellar curcumin 40 mg orally, one capsule twice daily for 3 months, in addition to standard treatment. The investigational product is SinaCurcumin, containing 40 mg of curcumin in a nano-micellar formulation.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Participants in this group will receive placebo orally, one capsule twice daily for 3 months, in addition to standard treatment. The placebo will be identical to the nano-micellar curcumin formulation in terms of appearance, color, size, and packaging.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Reza Educational, Research and Medical Complex
**Full name of responsible person**
Zinat Heidari
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**2**

**Recruitment center**

**Name of recruitment center**
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**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Mohsen Tafaghodi

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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**
Research Deputy 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**
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**Full name of responsible person**
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**Position**
Assistant professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Medical Pharmacy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
At the end of study, all medical records of patients will be shared.
**When the data will become available and for how long**
The access period starts 6 months after the publication.
**To whom data/document is available**
Researchers affiliated to academic, scientific and industrial institutes
**Under which criteria data/document could be used**
No one is allowed to use the documents except the principal researcher.
**From where data/document is obtainable**
Send an email to Dr. Zinat Heidari. heidarizn@mums.ac.ir
**What processes are involved for a request to access data/document**
Send an email to Dr. Zinat Heidari. heidarizn@mums.ac.ir
**Comments**