

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of Curcumin as add-on therapy in patients with Parkinson's disease on MDS-UPDRS scale: A Randomized Double-blind Placebo-controlled Trial

#### Protocol summary

##### Study aim

Evaluation of Curcumin as add-on therapy in patients with Parkinson's disease

##### Design

In this clinical trial 60 Patients with Parkinson's disease are allocated based on simple randomization using sealed envelopes. Patients, researcher, outcome assessor and data analyzer are blind to patient allocation to research groups.

##### Settings and conduct

This study will take place in Ghaem hospital of Mashhad University of Medical Sciences. Patients, researcher, outcome assessor and data analyzer are blind to patient allocation to research groups. The randomly selected sealed envelope is received by an oriented person other than researcher, outcome assessor or data analyzer who give the patients drug or placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who are diagnosed with Parkinson's disease based on MDS clinical diagnostic criteria for Parkinson's disease and at least 30 years of age 2. Patients who are receiving dopaminergic treatment and their symptoms are under control 3. Patients with signed informed consent Exclusion criteria: 1. Severe systemic or psychologic disease 2. History of Gastrointestinal bleeding 3. Aspirin use over 325mg/day, any anticoagulant or anti-platelet drug use such as heparin or warfarin, antioxidant use except vitamin E up to 2000 IU/day and vitamin C up to 500mg/day

##### Intervention groups

In this study patients allocated to drug or placebo groups. In drug group patients receiving Curcumin in Nanomicelles form as SinaCurcumin for 9 months with 80mg/day dosage in addition to their dopaminergic treatment. Placebo group receives placebo as same as drug group.

##### Main outcome variables

Patients score on MDS-UPDRS (Movement Disorders Society-Unified Parkinson's disease Rating Scale) scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171123037600N1**

Registration date: **2018-06-08, 1397/03/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-08, 1397/03/18**

Update count: **0**

##### Registration date

2018-06-08, 1397/03/18

##### Registrant information

##### Name

Hamidreza Ghodsi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3883 3080

##### Email address

ghodsihr901@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2018-06-20, 1397/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of Curcumin as add-on therapy in patients with Parkinson's disease on MDS-UPDRS scale: A Randomized Double-blind Placebo-controlled Trial

**Public title**  
Effectiveness of Curcumin in patients with Parkinson's disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients who are diagnosed with Parkinson's disease based on MDS clinical diagnostic criteria for Parkinson's disease and at least 30 years of age Patients who are receiving dopaminergic treatment and their symptoms are under control Patients with signed informed consent  
**Exclusion criteria:**  
Severe systemic or psychologic disease History of Gastrointestinal bleeding Aspirin use over 325mg/day, any anticoagulant or anti-platelet drug use such as heparin or warfarin, antioxidant use except vitamin E up to 2000 IU/day and vitamin C up to 500mg/day

**Age**  
From **30 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

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

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study we will use simple randomization and sealed envelopes. Patients are allocated based on selection of envelopes with "drug group" or "placebo group" written inside and are randomly arranged by another person other than researcher or data analyzer. allocation concealment is reached through randomization via sealed envelopes that randomly arranged and selected by third person who is giving drug or placebo to the patients.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients, researcher, outcome assessor and data analyzer are blind to patient allocation to research groups. The randomly selected envelope is received by an oriented person other than researcher, outcome assessor or data analyzer who give the patients drug or

placebo. Patients, researcher, outcome assessor and data analyzer never get access to the allocation information until the end of study.

**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**  
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
99191-91778

**Approval date**  
2017-07-05, 1396/04/14

**Ethics committee reference number**  
ir.mums.fm.rec.1396.48

**Health conditions studied**

**1**

**Description of health condition studied**  
Parkinson's disease

**ICD-10 code**  
G20

**ICD-10 code description**  
Parkinson's disease

**Primary outcomes**

**1**

**Description**  
Patients score in MDS-UPDRS (Movement Disorder Society-Unified Parkinson's Disease Rating) scale

**Timepoint**  
beginning of study, 3 months after drug initiation, 6 months after drug initiation, 9 months after drug initiation

**Method of measurement**  
MDS-UPDRS (Movement Disorder Society-Unified Parkinson's Disease Rating) scale which is a based on standard questionnaire, interview and neurological examination of the patients.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Curcumin in form of nanomicelles (SinaCurcumin) as add-on therapy for 9 months with 80mg/day dosage

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo drug identical to SinaCurcumin is given to patients beside their dopaminergic treatment for 9 months daily

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Hamidreza Ghodsi

##### Street address

Ahmadabad Ave., Ghaem Hospital of Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91766-99199

##### Phone

+98 51 3840 0000

##### Email

Ghodsahr901@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Tafaghodi

##### Street address

18th Daneshgah Street, Daneshgah Ave., Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

#### Postal code

9177948564

#### Phone

+98 51 3841 1538

#### Fax

+98 51 3843 0249

#### Email

vcresearch@mums.ac.ir

#### Web page address

<http://v-research.mums.ac.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Vice chancellor of research and technology 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

Hamidreza Ghodsi

##### Position

Student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

No 9, North Kowsar 3, Valkilabad Blvd., Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9178684993

##### Phone

+98 51 3883 3080

##### Email

Ghodsahr901@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

**Full name of responsible person**

Ali Shoeibi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neuroscience

**Street address**

No. 5, Samaneh street 21, Ferdowsi Blvd., Mashhad

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**Email**

shoeibia@mums.ac.ir

ghodsihr901@mums.ac.ir

**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**

These files could be available upon request: Patients' data after removing their identity Research protocol Statistical methods used in this study Informed consent file Research study report Codes used for allocating and data analyzing data categorizing file

**When the data will become available and for how long**

data availability would begin 3 months after article has been published

**To whom data/document is available**

Any researcher who needs our data to accomplish his research

**Under which criteria data/document could be used**

Researcher should use these data only in their related research and mention the reference

**From where data/document is obtainable**

researchers should send their request to Mr. Hamidreza Ghodsi by email or mail post. Email: ghodsihr901@mums.ac.ir Address: Block 9, North Kowsar street 3rd, Mashhad, Iran

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

Researchers should send their request with information about their goals and protocol of their study and how our data is needed for their results. requests will be responded in 14 working days.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hamideza Ghodsi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No. 9, North Kowsar 3, Vakilabad Blvd., Mashhad, Iran

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