

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 analyzer

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

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Email

Ghodsihr901@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

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Fax

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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

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9178684993

Phone

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Email

Ghodsihr901@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

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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

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

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