Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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
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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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18th Daneshgah Street, Daneshgah Ave., Mashhad, Iran
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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
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Other areas of specialty/work
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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
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