

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of curcumin nanomicelles on quality of life, severity of illness, fatigue and sleep quality in Parkinson's patients

Protocol summary

Study aim

Determining the effect of curcumin nanomicelles on quality of life, severity of illness, fatigue and sleep quality in Parkinson's patients

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment. A restricted randomization using random allocation rule method was used. Sequential numbered, sealed, opaque envelopes were used to allocation concealment.

Settings and conduct

Two-blind randomized clinical trial, and pre- and post-tests with control group. A total of 50 patients who were referred to Vali-e-Asr Hospital in Zanjan were selected and randomly divided into two experimental groups. All patients, referral physician, nurse, statistician, and the person responsible for drafting manuscript did not know any information about drug or placebo. Quality of life, fatigue, and sleep quality are based on PDQ-39 questionnaire, FSS, and PSQI, respectively. Two soft gelatin capsules of 80 mg after breakfast and dinner for three months are consumed.

Participants/Inclusion and exclusion criteria

Inclusion criteria Idiopathic Parkinson's disease (MDS-PD Criteria); At least elementary education; Filling up the consent form for each patient Unified Parkinson's Disease Rating Scale (Hoehn &Yahr) (I- III); No change in drug and supplement therapy since last month; 35 yrs and over; No reported allergy to turmeric and other foods and supplements; Parkinson's disease history<10 years
Exclusion criteria Abnormal renal and liver function tests; Cognitive disorders, epilepsy, stroke, and other cerebral diseases; Severe disability caused by dementia or other diseases; Gastric disorders, GE reflux and gastric ulcers

Intervention groups

Experimental (25 patients) and placebo (25 patients) groups, who, in addition to regular treatment, received curcumin and placebo , respectively, for three months.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101209005352N2**

Registration date: **2018-08-31, 1397/06/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-31, 1397/06/09**

Update count: **0**

Registration date

2018-08-31, 1397/06/09

Registrant information

Name

Mehdi Maghbooli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 2576

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of curcumin nanomicelles on quality of life, severity of illness, fatigue and sleep quality in Parkinson's patients

Public title

The effectiveness of curcumin on quality of life, severity of illness, fatigue and sleep quality in Parkinson's patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Idiopathic Parkinson disease (MDS-PD Criteria) At least elementary education Filling up the consent form for each patient Unified Parkinson's Disease Rating Scale (Hoehn &Yahr) (I- III) No change in drug and supplement therapy since last month 35 yrs and over No reported allergy to turmeric and other foods and supplements Parkinson's disease history <10 years

Exclusion criteria:

Abnormal renal and liver function tests Cognitive disorders, epilepsy, stroke, and other cerebral diseases Severe disability caused by dementia or other diseases Gastric disorders, GE reflux and gastric ulcers

Age

From **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a restricted randomization using random allocation rule method was used. This method represents a large block for the entire sample size, which means that the balances in the number of people assigned to each of the groups will be at the end of the study. Therefore, a sample size of 50 was determined and randomly assigned 25 persons to group A and 25 persons to group B. SAS software for randomization was used. Sequential numbered, sealed, opaque envelopes were used to allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. All patients know that there is two groups of patients that one group receiving drug and the other receiving placebo but they did not know any information about receiving drug or placebo. 2. The nurse responsible for filling the evaluation form know that there is two groups of patients that receiving drug or placebo but she did not know any information about who of them receiving

drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Vali-e-Asr Squ., Vali-e-Asr hospital

City

Zanjan

Province

Zanjan

Postal code

4515777978

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

ZUMS.REC.1396.249

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

Quality of life based on the PDQ-39 questionnaire

Timepoint

Filling up the questionnaire for each patient at the beginning of the study and three months later

Method of measurement

The quality of life based on the PDQ-39

Secondary outcomes

1

Description

sleep quality

Timepoint

Filling up the questionnaire for each patient at the beginning of the study and three month later

Method of measurement

The sleep quality based on PSQI questionnaire

2

Description

Fatigue

Timepoint

Filling up the questionnaire for each patient at the beginning of the study and three month later

Method of measurement

The fatigue based on FSS questionnaire

Intervention groups

1

Description

"Intervention group": Parkinson patients, two soft gelatin Sina-curcumin nanomicelle capsules of 80 mg after breakfast and dinner for three month , Exir Nano Sina company, Minoos company, Curcumin the yellow pigment in curry spice , Tumeric, is the principal curcuminoid in the rhizome of Curcuma longa Linn. Curcumin has effects similar to other polyphenols (diarylheptanoid). In combination with other main curcuminoids including desmethoxycurcumin, bis-desmethoxycurcumin, they form 3-5% of dried tumeric powder.

Category

Treatment - Drugs

2

Description

"Control group": Parkinson patients, two soft gelatin placebo Sina-curcumin nanomicelle capsules of 80 mg after breakfast and dinner for three month, Exir Nano Sina company, Minoos company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr hospital

Full name of responsible person

Maryam Dashti

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Vali-e-Asr Squ., Vali-e-Asr hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mehdi Maghbooli

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

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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

The total potential data can be shared after the removal of the patient's name.

When the data will become available and for how long

The start of the access period is 6 months after the results are published.

To whom data/document is available

Data will only be available to academic researchers.

Under which criteria data/document could be used

Different analyses are available for academic researchers.

From where data/document is obtainable

Dr. Mehdi Moghbouli, Vali-e-Asr Square, Vali-e-Asr hospital, Zanjan, 4515777978 Iran, Tel: 00982433770801, e-mail address: m.maghbooli@zums.ac.ir

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

Send request via email - Duration of sending data: two weeks

Comments