Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Email address

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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 pacebo 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 paients that receiving drug or pacebo but she did not know any information about who of yhem receiveing 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, Minoo comany, Curcumin the yellow pigment in curry spice , Tumeric, is the principal curcuminoid in the rhizome of Curcumia longa Linn. Curcumin has effects similar to other polyphenols (diarylheptanoid). In combination with other main curcuminoids including desmethoxycurcumin, bis-desmethoxycurumin, they form 3-5% ofdried tumeric powder.
Category
Treatment - Drugs

2

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr hospital
Full name of responsible person
Maryam Dashti
Street address
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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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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

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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