

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of a capsule prepared from the aqueous extract of Terminalia Chebula on catatonia in patients with Parkinson's disease

Protocol summary

Study aim

Determining the therapeutic effect of Terminalia Chebula extract in the treatment of Parkinson's disease catatonia in patients referred to Boali Hospital in Tehran

Design

Clinical trials with control group, Parkinson's disease, with parallel groups, blind, randomized

Settings and conduct

In this double-blind clinical trial study, a total of 50 patients with Parkinson's disease who referred to the neurology clinic of Bu Ali Hospital were included in each treatment group and control group (placebo). These individuals were included in the study in such a way that at the beginning of the study, the intervention group, in addition to receiving L-dopa treatment, were given capsules containing herbal medicine to take one every 12 hours and the control group, in addition to receiving L-dopa treatment, placebo. Have received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 30 years of age with Parkinson's Age under 70 years Patients who have been definitively diagnosed by a Parkinson's neurologist Patients who have had symptoms for less than 3 months. Exclusion criteria: Age over 70 years Age under 30 years Uncertain diagnosis of Parkinson's Has had Parkinson's symptoms for more than 3 months and has not been diagnosed

Intervention groups

Terminalia Chebula extract capsule group: In addition to the main treatment for Parkinson's disease, which is L-dopa judgment, patients were given capsules containing Terminalia Chebula and patients were advised to take 1 every 12 hours. 2, 4 and 6 weeks after the first visit were performed in the next visits and the patients were catatonically evaluated during the night rest and during daily activities, the next visit tests were evaluated and the relevant results were recorded in the questionnaires.

Main outcome variables

Catatonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201029049187N1**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **retrospective**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Hesam Adin Atashi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7798 4996

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-10-21, 1391/07/30

Expected recruitment end date

2013-01-27, 1391/11/08

Actual recruitment start date

2012-09-24, 1391/07/03

Actual recruitment end date

2013-02-13, 1391/11/25

Trial completion date

2013-02-13, 1391/11/25

Scientific title

The effect of a capsule prepared from the aqueous extract of Terminalia Chebula on catatonia in patients with Parkinson's disease

Public title

Therapeutic effect of Terminalia Chebula extract on Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 30 years of age with Parkinson's Age under 70 years Patients who have been definitively diagnosed by a Parkinson's neurologist Patients who have had symptoms for less than 3 months

Exclusion criteria:

Age over 70 years Age under 30 years Uncertain diagnosis of Parkinson's Has had Parkinson's symptoms for more than 3 months and has not been diagnosed

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 50 patients with Parkinson's disease were selected by simple randomization and divided into case and control groups. In order to collect data, eligible patients who participated in the study were randomly and bi-blindly assigned by the project secretary to two groups receiving capsules containing Terminalia Chebula (in the treatment group) and Placebo capsules were divided into control group. These drugs were placed in two packages (package A, package B) and were given to patients according to the division of people into two groups. None of the patients knew about the type of medicine in the packages and the concealment was done correctly. In this type of sampling, each member of the community is given an equal chance to be selected in the sample. In order to select a simple random sample by lottery method, according to the sampling framework from among the members of the community, a sample with the desired sample size should be selected from the people listed by lot. In the lottery method, we wrote the names of the people on a piece of paper and placed them inside the box, then took out the papers one by one until the desired sample size was completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, 4 groups of patients, clinical caregiver,

outcome assessor and data analyzer were kept blind. None of these men knew which containers contained the Black Halil capsule or the placebo capsule. Blinding was performed carefully in this study so that the patients were divided into two groups by the project secretary receiving capsules containing Terminalia Chebula (in the treatment group) and placebo capsules in the control group. These drugs were placed in two packages (package A, package B) and were given to patients according to the division of people into two groups. None of the patients knew about the type of medicine in the packages and the concealment was done correctly. None of the drugs were disclosed to patients, clinicians, outcome assessors, and data analyzers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Islamic Azad University of Medical Sciences, Tehran, Iran

Street address

Tehran Medical Branch, Islamic Azad University, Khaghani st, Shari'ati Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19395/1495

Approval date

2012-09-21, 1391/06/31

Ethics committee reference number

14085

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

Parkinson's catatonia

Timepoint

Before the intervention and week 2, 4, 6 after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Quality of life Score and Symptoms

Timepoint

Before the start of the study and 2 months after the start of the study

Method of measurement

Parkinson's Disease Questionnaire =PDQ-39

Intervention groups

1

Description

Intervention group: Terminalia Chebula extract capsule group: In addition to the main treatment for Parkinson's disease, which is L-dopa judgment, patients were given capsules containing Terminalia Chebula and patients were advised to take 1 every 12 hours. 2, 4 and 6 weeks after the first visit were performed in the next visits and the patients were catatonically evaluated during the night rest and during daily activities, the next visit tests were evaluated and the relevant results were recorded in the questionnaires. According to the method (Morpurgo 10), the catatonic progression and its reduction are examined by observing the patient's movements and assigning points.

Category

Treatment - Drugs

2

Description

Control group: Group receiving placebo: In this group, patients are given placebo and in addition to receiving L-dopa treatment, patients were told to take one placebo capsule every 12 hours. It should be noted that patients are completely blind and do not know that drugs are placebo. Follow-up of patients was performed in 2, 4 and 6 weeks after the first visit in the next visits, respectively, and the patients were catatonically evaluated during the night rest and during daily activities, testing of the next visits and recording the relevant results in the questionnaires. Been. According to the method (Morpurgo 10), the catatonic progression and its reduction are examined by observing the patient's movements and assigning points.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali hospital

Full name of responsible person

Dr. Mehdi Vahid Dastjerdi

Street address

Buali Hospital, Damavand Avenue, Imam Hossein Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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?

No

Title of funding source

Office of Research, Tehran Islamic Azad University

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

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Mehdi Vahid Dastjerdi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Contact

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Position

MD

Latest degree

Medical doctor

Other areas of specialty/work

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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

All data can be shared after identifying individuals. The effect of capsules containing Terminalia Chebula extract in the treatment of Parkinson's catatonia is shared. Sharing all the data and documents of this study to people who are conducting similar studies or are interested in paying more attention to this study is unrestricted.

When the data will become available and for how long

After publishing the manuscript in a for 1 year later

To whom data/document is available

All researchers, have no limits

Under which criteria data/document could be used

Provided that the researcher wants to do the same or be interested in further study of this study.

From where data/document is obtainable

Correspond to the research

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

Email to Person responsible, Checked by the responsible, Providing information

Comments