# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 Booali 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)
**Phone**
+98 21 7798 4996
**Email address**
h.atashi@student.iautmu.ac.ir

**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'sAge 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

**City**

Tehran

**Province**

Tehran

**Postal code**

19395/1495

**Phone**

+98 21 3334 8036

**Email**

Bouali-hospital@iautmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Farshad Hashemian

**Street address**

Tehran Azad University of Medical Sciences, Khaghani St., Shariati St

**City**

Tehran

**Province**

Tehran

**Postal code**

1916893813

**Phone**

+98 21 2200 6660

**Email**

iautmu@iautmu.ac.ir

**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**

Academic

## 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**
Neurology

**Street address**
Bu'ali Hospital, Damavand Ave, Imam Hossein Square, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
17117

**Phone**
+98 21 3334 8036

**Email**
Mvdastjerdi@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Islamic Azad University

**Full name of responsible person**
Hesam Adin Atashi

**Position**
MD

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Neurology

**Street address**
Bu'ali Hospital, Damavand Ave, Imam Hossein Square, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
17117

**Phone**
+98 21 3334 8036

**Email**
h.atashi@student.iautmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Islamic Azad University

**Full name of responsible person**
Hesam Adin Atashi

**Position**
MD

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Neurology

**Street address**
No. 6, Shahid Beani St., Avicenna Square, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1151811518

**Phone**
+98 937 650 6313

**Email**
h.atashi@student.iautmu.ac.ir

## 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**