# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Evaluating the effect of black myrobalan fruit (Terminalia Chebula Retz.) on cognitive impairments, and positive and negative symptoms in patients with chronic schizophrenia

## Protocol summary

**Study aim**
The aim of this study is to evaluate the effect of black myrobalan fruit (Terminalia Chebula Retz.) on cognitive impairments, and positive and negative symptoms in patients with chronic schizophrenia

**Design**
this study is a randomized, double-blind, controlled clinical trial with a parallel group design of 50 patients.

**Settings and conduct**
Patients are selected from Kerman Golestan Health Center. Participants and a physician are blinded with similar placebo and black myrobalan capsules,

**Participants/Inclusion and exclusion criteria**
The inclusion criteria are hospitalized patients with chronic schizophrenia based on DSM-IV criteria, and having no significant change in medication or symptoms over the previous 2 months Exclusion criteria are mental retardation, substance dependence, and history of significant medical illness.

**Intervention groups**
Powdered black myrobalan fruit with almond oil (10% w/w) (in intervention group) and starch as placebo (in control group) are administered as three 500 mg capsule twice daily for four weeks.

**Main outcome variables**
Positive and negative symptoms and cognitive function are measured with Positive and Negative Syndrome Scale (PANSS) and Screen for Cognitive Impairment in Psychiatry (SCIP) questionnaires at baseline and after four weeks.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20110310006026N7**
Registration date: **2018-04-07, 1397/01/18**
Registration timing: **prospective**

Last update: **2018-04-07, 1397/01/18**
Update count: **0**

**Registration date**
2018-04-07, 1397/01/18

**Registrant information**

**Name**
Fatemeh Dabaghzadeh

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 34 3132 5034

**Email address**
dabaghzadeh@razi.tums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-05-01, 1397/02/11

**Expected recruitment end date**
2019-05-01, 1398/02/11

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluating the effect of black myrobalan fruit (Terminalia Chebula Retz.) on cognitive impairments, and positive and negative symptoms in patients with chronic schizophrenia

**Public title**
Evaluating the effect of black myrobalan fruit (Terminalia Chebula Retz.) on cognitive impairments, and positive and negative symptoms in patients with chronic schizophrenia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Hospitalized patients with chronic schizophrenia based on DSM-IV criteria Having no significant change in medication or symptoms over the previous 2 months
**Exclusion criteria:**
Mental retardation Substance dependence History of significant medical illness
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **50**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Block randomization
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Participants and physician: black myrobalan and placebo capsules had the same shape, color and outer packaging.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Kerman University of Medical Sciences
**Street address**
Beginning of Jahad Blvd., Tahmasebad Fourways
**City**
Kerman
**Province**
Kerman
**Postal code**
7619813159
**Approval date**
2018-03-17, 1396/12/26
**Ethics committee reference number**
IR.KMU.REC.1396.2491

## Health conditions studied

### 1

**Description of health condition studied**
Chronic schizophrenia
**ICD-10 code**
F20
**ICD-10 code description**
Schizophrenia

## Primary outcomes

### 1

**Description**
Cognitive functions
**Timepoint**
At baseline and 4 weeks after intervention
**Method of measurement**
Screen for Cognitive Impairment in Psychiatry (SCIP) questionnaire

### 2

**Description**
Positive and negative symptoms
**Timepoint**
At baseline and 4 weeks after intervention
**Method of measurement**
Positive and Negative Syndrome Scale (PANSS) questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Powdered black myrobalan fruit with almond oil (10% w/w) are administered as three 500 mg capsule twice daily for four weeks.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: starch as placebo (in control group) are administered as three 500 mg capsule twice daily for four weeks.
**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Kerman Golestan Health Center
**Full name of responsible person**
Fatemeh Dabaghzadeh
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Abbas Pardakhtyi
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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**
Kerman 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**
Kerman University of Medical Sciences
**Full name of responsible person**
Fatemeh Dabaghzadeh
**Position**
Assistant professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
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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)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no further information
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available