

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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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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

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 Pardakhty

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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

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

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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