Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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)

Phone
+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
Street address
Haft bagh high way
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5212
Email
fatemeh_dabaghzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhtyi
Street address
Beginning of Jahad Blvd., Tahmasebad Fourways
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3815
Email
abpardakhty@kmu.ac.ir

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
Street address
Haft bagh high way
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5001
Email
fatemeh_dabaghzadeh@yahoo.com

Person responsible for scientific 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
Street address
Haft bagh high way
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5001
Email
fatemeh_dabaghzadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Kerman University of Medical Sciences

Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Haft bagh high way
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5001
Email
fatemeh_dabaghzadeh@yahoo.com

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