

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of Berberry root (*Berberis vulgaris*) as Adjuvant Treatment on the prevention of atypical Antipsychotic-Induced metabolic syndrome in Patients With Schizophrenia: A triple-blind, Randomized, Placebo-controlled Trial

Protocol summary

Study aim

Evaluation of barberry root (*Berberis Vulgaris*) effect as an adjunct on prevention of metabolic syndrome caused by atypical antipsychotic drugs in patients with schizophrenia: a three-blind placebo-controlled clinical trial.

Design

Clinical trial with control group, three-way blind, randomized, phase 3 on 106 patients, randomized permutation block method with block size 6 (using random permutation table) is used for randomization.

Settings and conduct

Study of a three-way randomized clinical trial of patients with schizophrenia diagnosed by two psychiatrists based on DSM-V 28 and SCID-5 29 questionnaire, randomized to case and control groups, to case group of barberry root capsule, three times a day This extract is loaded as a study drug in 500 mg capsules. control group is given the same amount of placebo capsule that was prepared from starch powder with the permitted color in a similar way to the drug powder and loaded in similar capsules, over a period of three months, and finally evaluated the effect of the drug on symptoms. By fasting blood glucose, serum fats, blood pressure and waist circumference are repeated at end of the third month

Participants/Inclusion and exclusion criteria

Entry requirements: 18 to 55 years old with a diagnosis of schizophrenia non-entry: any side effects

Intervention groups

Case group is given 500 mg capsules of barberry root three times a day. control group is given the same amount of placebo capsule as the prepared dye starch powder in the same way as the drug powder. It is given over a period of three months, and finally the effect of the drug on symptoms is measured by measuring fasting blood glucose. Serum fats (triglyceride cholesterol),

blood pressure and waist measurements are repeated at the end of the third month

Main outcome variables

Determination of changes in triglycerides, sugar, waist size, cholesterol, blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210425051074N1**

Registration date: **2021-06-15, 1400/03/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-15, 1400/03/25**

Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Farzaneh Babaali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3321 4578

Email address

f.babaali957@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Berberry root (*Berberis vulgaris*) as Adjuvant Treatment on the prevention of atypical Antipsychotic-Induced metabolic syndrome in Patients With Schizophrenia: A triple-blind, Randomized, Placebo-controlled Trial

Public title

The effect of barberry root on schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Early diagnosis of schizophrenia They must have recently sought treatment or not received any medication in the past three months Study subjects should be screened for metabolic syndrome. In fact, all patients should be screened for glucose levels, blood lipids, blood pressure, and waist circumference, and ultimately only those with no or at most two of these symptoms should be included in the study The patient is able to take medicine Receive written consent from the patient or parents to enter the study

Exclusion criteria:

Pregnant and lactating women Incidence of any side effects of the drug) stomach pain, diarrhea, constipation, bloating, headache, skin complications Existence of any severe and chronic physical diseases (brain, cardiovascular, neurological and seizure diseases, liver, diabetes, hypertension, hyperlipidemia, joints or history of substance use) Mental retardation People treated with antihypertensives, antihypertensives, anticoagulants, sedatives, and drugs that are metabolized by the liver.

AgeFrom **18 years** old to **55 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample sizeTarget sample size: **106****Randomization (investigator's opinion)**

Randomized

Randomization description

The method of assigning the intervention to individuals is random and the method of random permutation blocks with block size 6 (using the table related to random

permutations). In the random method, people without a specific pattern or order are included in the study based on the inclusion criteria. Blocking is done to balance the number of samples and the size of both blocks is equal. In this study, patients are treated with medication packages pre-determined by the study supervisor (supervisor). The drug packages are quite similar in shape and the patient and the executor of the project are not aware of the contents of the packages.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are treated with medication packages pre-determined by the study supervisor (supervisor). The drug packages are quite similar in shape and the patient and the executor are not aware of the contents of the packages. In addition, data collection, patient assessment and completion of forms is done by the project manager and his assistant who are not aware of the contents of the package. In the data analysis stage, the analysis will be performed by the project consultant and the project manager who are not aware of the contents of the drug packages and only the patient group (group 1 or 2) will be identified for data analysis. Therefore, the study is 3-blind and the contents of the two drug groups are not clear from the stage of patient admission to the study, data collection and analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz University of Medical Sciences - Golestan Research and Treatment Center (R)

Street address

Golestan hospital , Farvadin Ave , Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.001

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

cholesterol

Timepoint

At the beginning of the study and three months later

Method of measurement

blood sample

2

Description

triglyceride

Timepoint

At the beginning of the study and three months later

Method of measurement

blood sample

3

Description

blood pressure

Timepoint

At the beginning of the study and three months later

Method of measurement

Hand pressure gauge

4

Description

blood sugar

Timepoint

At the beginning of the study and three months later

Method of measurement

blood sample

Secondary outcomes

1

Description

cholesterol

Timepoint

At the beginning of the study and 3 months later

Method of measurement

blood sample

2

Description

blood pressure

Timepoint

At the beginning of the study and 3 months later

Method of measurement

Hand pressure gauge

3

Description

blood sugar

Timepoint

At the beginning of the study and 3 months later

Method of measurement

blood sample

4

Description

Waist size

Timepoint

At the beginning of the study and 3 months later

Method of measurement

meter

5

Description

triglyceride

Timepoint

At the beginning of the study and 3 months later

Method of measurement

blood sample

Intervention groups

1

Description

Intervention group: After obtaining written consent and explaining the study conditions, patients are asked to complete a demographic questionnaire that includes age, sex, duration of illness, as well as the use of any medication. The case group is given barberry root capsule, which is made in Ahvaz Medicinal Plants Research Center, three times a day for three months. This extract has been loaded as a study drug in 500 mg capsules

Category

Treatment - Drugs

2

Description

Control group: After obtaining written consent and explaining the study conditions, patients are asked to complete a demographic questionnaire that includes age, sex, duration of illness, as well as the use of any drug. It is prepared from starch powder with the allowed color in a similar way to medicinal powder. It is loaded in similar capsules and is made in Ahvaz Medicinal Plants Research Center. It is given for a period of three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Farzaneh Babaali

Street address

Golestan hospital ,Farvardin Ave ,Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3038

Email

F.babaali957@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Sahand Jorfi

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715751

Phone

+98 61 3311 3848

Email

sahand369@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Hamzeh Rostami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ahvaz Golestan Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3038

Email

rostami-h@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hamzeh Rostami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ahvaz Golestan Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3038

Email

rostami-h@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hamzeh Rostami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Ahvaz Golestan Hospital

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3038

Email

rostami-h@ajums.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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The data can not be shared after identifying individuals, and only part of the main outcome can be shared.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data are allowed for clinical trials by industry professionals and academic researchers

From where data/document is obtainable

Provide clear contact information, including mailing addresses for correspondence, or e-mail addresses, or websites, and telephone and fax numbers, along with the names and addresses of those responsible.

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

The applicant must provide the title and abstract of his / her plan along with the exact address

Comments