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

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Iran (Islamic Republic of)

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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.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target 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
cholestrol
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 suger
Timepoint
At the beginning of the study and three months later
Method of measurement
blood sample

Secondary outcomes

1

Description
cholestrol
Timepoint
At the beginning of the study and 3 months later
Method of measurement
blood sample

2

Description
blood pressur
Timepoint
At the beginning of the study and 3 months later
Method of measurement
Hand pressure gauge

3

Description
blood suger
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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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
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Person responsible for updating data

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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