Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of Schizoherb on atypical antipsychotics-induced weight gain in patients with schizophrenia

Protocol summary

Study aim
The effect of herbal medicine Schizoherb on the weight of patients with schizophrenia receiving atypical antipsychotic

Design
This is a triple blind randomised controlled trial. Patients are divided into control and intervention groups using random blocking method by www.sealedenvelop.com. Opaque sealed envelopes are used for allocation concealment. The sample size is 32 patients in each group.

Settings and conduct
Schizophrenic patients referred to the clinic of Ibn Sina Hospital in Mashhad, who are eligible for admission, are randomly divided into two groups of intervention and control for 8 weeks. Biochemical lab tests and measurement of body weight and blood pressure and completion of the 36-item WHOQol questionnaire and PANSS questionnaire are performed at the beginning and end of the study for patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with schizophrenia aged 18 to 65 years, receiving second-generation antipsychotics who do not have serious systemic disease (including liver or kidney failure, known heart disease, hypothyroidism, hypertension) and have not changed the type and dose of antipsychotic medication for at least the past 3 months. . Criteria for non-entry: 1- Dependence on substances (except cigarettes) 2- Women during pregnancy or lactation 3- Liver tests more than twice normal 4- Sensitivity to any of the design plants

Intervention groups
Intervention group: with continuation of antipsychotic drug, administration of 700 mg schizoherb herbal capsule, twice a day for 8 weeks Control group: with continuation of antipsychotic drug, administration of placebo capsules, twice a day for 8 weeks

Main outcome variables
weight

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210707051813N1**
Registration date: **2021-08-21, 1400/05/30**
Registration timing: **prospective**

Last update: **2021-08-21, 1400/05/30**
Update count: **0**

Registration date
2021-08-21, 1400/05/30

Registrant information

Name
Hamideh Naghibi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3711 2701

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation the effect of Schizoherb on atypical antipsychotics-induced weight gain in patients with schizophrenia

Public title

"Effect of Schizoherb on atypical antipsychotics-induced weight gain"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 65 years No serious systemic disease (including liver or kidney failure, known heart disease, hypothyroidism, hypertension) based on history and physical examination and lab tests and approved by a psychiatrist No changes in the type and dose of antipsychotic drug in at least the last 3 months

Exclusion criteria:

Dependence on substances (except cigarettes) Women during pregnancy or lactation Liver functional tests more than twice normal History of allergies to any of the plants in the design Consumers of aripiprazole

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Using sealedenvelope.com and random blocking method, patients are placed in the intervention or control group. 16 blocks of 4 will be produced and the sequence produced by the design statistician will be placed in opaque sealed envelopes and numbered, respectively.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is three-blinded (blinding the subjects, evaluators and analysts). Instead of the intervention and control group, A and B are used to blind the analyst. The outcome assessor is someone outside the research group. The intervention group is given Schizoherb herbal capsules in addition to previous medications and the control group is given placebo capsules in addition to previous medications.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Daneshgah Street

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mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2021-06-19, 1400/03/29

Ethics committee reference number

IR.MUMS.REC.1400.075

Health conditions studied

1

Description of health condition studied

Weight gain side effect in patients with schizophrenia receiving atypical antipsychotics

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

weight

Timepoint

Before the beginning of study (week zero) and the end of study (week eight)

Method of measurement

Measuring body weight (in kilograms) and height (in meters) and calculating body mass index or BMI (in kg / m2), measuring waist circumference with a tape measure (in centimeters) and calculating WHR (waist-hip circumference ratio)

Secondary outcomes

1

Description

fasting blood suger

Timepoint

beginning and end of the study

Method of measurement

by blood sample (in mg/dl)

2

Description
lipid profile
Timepoint
beginning and end of the study
Method of measurement
by blood sample (in mg/dl)

3

Description
measuring blood pressure
Timepoint
beginning and end of the study
Method of measurement
Using a mercury barometer (in mmhg)

4

Description
Check the quality of life
Timepoint
beginning and end of the study
Method of measurement
Using the World Health Organization quality of life questionnaire (WHOQol - Bref)

5

Description
Evaluation of the severity of positive and negative symptoms of schizophrenia. (According to the available articles, the herbs used in the design are expected to be effective in reducing negative symptoms. In most interventional studies in schizophrenic patients, the severity of symptoms is assessed during the study.)
Timepoint
weeks 0, 4 , 8
Method of measurement
PANSS questionnaire

Intervention groups

1

Description
Simultaneously with the continuous use of antipsychotic drugs, in the intervention group, Schizoherb capsules (including three herbs green tea, Persian borage and portulaca oleracea, formulated in the laboratory of Mashhad School of Traditional and Complementary Medicine, Iran), in the form of 700 mg capsules are prescribed twice a day for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: In the control group, placebo capsules containing Avisel, made in the laboratory of Mashhad School of Traditional and Complementary Medicine, are added to the patient's treatment regimen for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina Psychiatric Hospital
Full name of responsible person
Mohammadreza Fayyazi bordbar
Street address
Ibn-e-Sina psychiatric Hospital, Horre ameli avenue, Boo-Ali square
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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University Street - Ghorashi Building of Mashhad University of Medical Sciences - Vice Chancellor for Research and Technology
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Web page address
http://v-research.mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Hamideh Naghibi

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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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
I have not decided yet - its release schedule is not yet known

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available