

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The efficacy of adding *Boswellia serrata* on cognitive impairment in patients with schizophrenia

Protocol summary

Study aim

The efficacy of adding *Boswellia serrata* on cognitive impairment in patients with schizophrenia

Design

Clinical trial with control and intervention groups, with parallel groups, double-blind, envelope randomized, phase 3 on 40 patients. Excel software rand function was used for randomization.

Settings and conduct

Forty hospitalized patients with a confirmed diagnosis of schizophrenia based on DSM5 referred to Ibn Sina Hospital who met the inclusion criteria were treated with standard schizophrenia including second-generation antipsychotics other than clozapine.

Participants/Inclusion and exclusion criteria

All patients with a confirmed diagnosis of schizophrenia according to DSM5. Age range 18 to 36 years. Completion of the consent form by their legal guardian. Patients should have a trusted caregiver who monitors the patient's medication use. Education level: At least 8 classes. No entry: Existence of serious accompanying cognitive disorders. Having other psychiatric disorders. Existence of other medical diseases that affect cognition, such as head trauma and epilepsy. Consumption of substances other than cigarettes. Pregnant or lactating patient. Do not have the ability and focus to perform tests.

Intervention groups

Intervention and control groups are divided. The intervention was administered in parallel with 750 mg capsules of frankincense resin 3 times a day and a placebo containing 750 mg of starch powder 3 times a day along with other available treatments for schizophrenia. Patients at the beginning of the study and after medication At weeks 6 and 12, they are assessed by PANSS, stroop, digit span, wisconsin, and Wechsler tests. But the control group does not have a placebo and they are placed under control.

Main outcome variables

Quality of life (quality variable) will be measured using the Shapiro-Wilk test questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N48**

Registration date: **2022-03-03, 1400/12/12**

Registration timing: **prospective**

Last update: **2022-03-03, 1400/12/12**

Update count: **0**

Registration date

2022-03-03, 1400/12/12

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-26, 1401/01/06

Expected recruitment end date

2022-06-27, 1401/04/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of adding Boswellia serrata on cognitive impairment in patients with schizophrenia

Public title

The efficacy of adding Boswellia serrata

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with a confirmed diagnosis of schizophrenia according to DSM5 Age range 18 to 36 years Completion of the consent form by their legal guardian. Patients should have a trusted caregiver who monitors the patient's medication use. Education level: At least 8 classes.

Exclusion criteria:

Existence of serious accompanying cognitive disorders. Having other psychiatric disorders. Existence of other medical diseases that affect cognition, such as head trauma and epilepsy Consumption of substances other than cigarettes Pregnant or lactating patient Do not have the ability and focus to perform tests

Age

From **18 years** old to **36 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This is how random numbers are prepared with the help of Randomize.com. According to the number of research samples, a number of envelopes with wrappers Alumni (in order to avoid the clarity of the contents of the envelopes), are prepared and each of the random sequences created on a card is recorded and the cards inside the envelopes are better named. In order to maintain a random sequence, also on the outer surface of the envelopes. The issuance number is done in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the envelopes have the odd number of the control group and the envelopes have an even number.

Blinding (investigator's opinion)

Double blinded

Blinding description

People under study and outcome assessor are fully aware of the subject of research and the purpose and process of the study, and after filling out the consent and according to the entry conditions, will enter the study of the contents of the envelope and to which group they are assigned (control and intervention) (Because they do not predict the outcome) will be unaware.

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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

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Postal code

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Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.553

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes**1****Description**

Patient quality of life

Timepoint

Before the intervention and after 3 months of drug use

Method of measurement

PANSS tests, stroop test, digit span, wisconsin, Wechsler memory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In parallel, by administering 750 mg capsules of frankincense resin 3 times a day and placebo containing 750 mg of starch powder 3 times a day along with other available treatments for schizophrenia. Weeks 6 and 12 are assessed by PANSS, stroop, digit span, wisconsin, and Wechsler tests

Category

Placebo

2

Description

Control group: They undergo existing treatments for schizophrenia and are assessed at 6 and 12 weeks by PANSS, stroop test, digit span, wisconsin, and Wechsler memory tests.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn-e-Sina psychiatric Hospital

Full name of responsible person

Mohammadreza Fayazibordbar

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,boo Ali square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

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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

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

Mohammadreza Fayazibordbar

Position

Profesor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Mohammadreza Fayazibordbar

Position

Profesor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

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