Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Scinces, 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 Randomaize.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
Mashhad
Province
Razavi Khorasan
Postal code
123456
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
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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
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Psychiatrics
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Person responsible for updating data

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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