

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

A comparative study of the effectiveness and safety of Aripiprazole and Olanzapine in patients with psychotic disorders; A clinical trial

Protocol summary

Study aim

Comparison of the effectiveness and safety of Aripiprazole or Olanzapine in psychotic patients

Design

Population of the clinical trial includes patients with psychotic disorders selected based on inclusion criteria. A phase 2 non-randomized controlled trial is conducted monitoring 94 patients.

Settings and conduct

The study population includes psychotic patients randomly divided into two blind groups. First, BMI tests and other relevant tests are done. Second, the positive and negative symptoms questionnaire is administered to the blind groups. Then, either Olanzapine or Aripiprazole is prescribed for the patients. After one month, the patients will be re-examined and their height and weight are measured again to control BMI and then the side effect questionnaire is filled out. After two months, the patients are examined again and the process of the first month is repeated. Finally, the information is analyzed using SPSS20 software.

Participants/Inclusion and exclusion criteria

Inclusion criteria :1) Diagnosing psychotic disorders through clinical interview and DSM5 and ICSDIII criteria 2) Prescribing Aripiprazole or Olanzapine as a treatment strategy 3) Patients aged 18.64 years. Exclusion criteria include: 1) People taking other medications such as sleeping pills with Aripiprazole or Olanzapine 2) Patients with dependence on or abuse of Aripiprazole or Olanzapine 3) Conditions contraindicated with Aripiprazole or Olanzapine.

Intervention groups

Psychotic patients referred to Farabi Hospital, Kermanshah

Main outcome variables

Body mass index, Efficacy of Olanzapine and Aripiprazole

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200430047250N1**

Registration date: **2020-09-11, 1399/06/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-11, 1399/06/21**

Update count: **0**

Registration date

2020-09-11, 1399/06/21

Registrant information

Name

Nima Gheitouly

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3428 3987

Email address

nimagheitouly@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-18, 1399/04/28

Expected recruitment end date

2021-07-08, 1400/04/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effectiveness and safety of Aripiprazole and Olanzapine in patients with psychotic disorders; A clinical trial

Public title

Evaluation of the efficacy of Olanzapine and Aripiprazole in patients with psychotic disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosing psychotic disorders through clinical interview and DSM-5 & ICD-III criteria Prescribing Aripiprazole or Olanzapine as a treatment strategy for psychotic disorders Patients aged 18-64 years

Exclusion criteria:

Patients simultaneously taking medications such as sleeping pills and Aripiprazole or Olanzapine (drugs that have high sedative effects) Patients suffering dependence on or abuse of Aripiprazole or Olanzapine Patients with multiple chronic physical illnesses such as Diabetes, High Blood Pressure, and Rheumatism Patients with certain health conditions(preventing them from taking Aripiprazole or Olanzapine)

Age

From **18 years** old to **64 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinded individuals include: Participants Trialist (project executive) Patients Health staff outcome adjudicators

Data Analysts

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah university of medical sciences

Street address

No48 ,Boostan Ave ,Roodaki Blvd, Kermanshah Town

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Province

Kermanshah

Postal code

6714847691

Approval date

2020-07-18, 1399/04/28

Ethics committee reference number

IR.KUMS.REC.1399.376

Health conditions studied

1

Description of health condition studied

Psychotic Disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measurement of body mass index in psychotic patients treated with olanzapine or aripiprazole

Timepoint

At the beginning of the study and one and two months after starting the drug

Method of measurement

Height and weight scales

2

Description

Efficacy of olanzapine and aripiprazole in psychotic patients

Timepoint

At the beginning of the study and one and two months after starting the drug

Method of measurement

PANSS Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study is a double-blind clinical

trial. The study population includes all patients with psychotic disorders who in 1398, referred to Farabi Hospital in Kermanshah for treatment and have the criteria for inclusion in the study Inclusion criteria in this study include (diagnosis of psychotic disorders based on clinical interview and DSMv criteria and ICD-III by a psychiatrist 2) Prescribing aripiprazole or olanzapine as a treatment strategy for psychotic disorders by a psychiatrist 3) In the age range of 18-64 years and exclusion criteria are also 1) People who take drugs such as hypnotics Take concomitantly with aripiprazole or olanzapine (drugs that have high sedative effects) 2) Patients who are abused or dependent on aripiprazole or olanzapine, 3) Patients with concomitant chronic physical illnesses such as diabetes, hypertension, And rheumatism 4) patients who are medically prohibited from taking aripiprazole or olanzapine. After explaining the purpose of the study, and obtaining informed consent, patients are randomly divided into two groups based on a table of random numbers. First, tests related to the presence or absence of metabolic syndrome, including blood sugar, blood lipids, etc. are taken from these people. Also, in order to measure body mass (BMI), height and weight of people are measured. Then, one of the members of the research team, who randomizes two groups of blinds, poses a questionnaire of positive and negative symptoms (PANSS) of these people. Becomes. In the next step, the psychiatrist prescribes one of the two drugs olanzapine and eripiprazole for the patient and provides the patient with the amount of the drug for one month. Also, the contact number is provided to the patient so that in case of any problem, he can discuss it with the psychiatrist. During the first month, patients are contacted once a week and asked about side effects. After one month, the contact number that was initially taken from the patient will be called and he will be asked to visit again. During this visit, the psychiatrist re-examines the patient and returns the medication. During this visit, the patient is sent back to the laboratory and the first stage tests are repeated for him. Also, his height and weight are re-evaluated by the first stage assessor to control body mass and PANSS questionnaire and side effects checklist based on DSMv Prepared is completed. Since the time required for the effect of these drugs is eight weeks or two months (14) after another month, ie after the end of two months, the patient is contacted again and the patient evaluation cycle, which was performed at the end of the first month, is repeated. It should be noted that if at the end of a month or the second month the patient has side effects or metabolic syndrome, the psychiatrist can change the patient based on the clinical condition. It is also used to control confounding variables such as the patient's arbitrary use of other drugs or to reduce the amount of drugs arbitrarily by calling the patient and reminding them. After two months, the information is entered in SPSS20 software and analyzed using statistical tests.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Adeleh Elahi

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Ashayer Ave, Dolatabad Blvd, Kermanshah Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Proportion provided by this source

90

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

nimagheitouly@yahoo.com

Contact

Name of organization / entity
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Position
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Person responsible for scientific inquiries

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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