

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of efficacy of celecoxib as add on to risperidone to reduce positive , negative and cognitive symptoms in schizophrenic patients in active phase: a double-blind, randomized and placebo-controlled clinical trial

Protocol summary

Study aim

The effect of adding celecoxib to risperidone to reduce positive, negative and cognitive symptoms in patients with acute phase schizophrenia

Design

Clinical trial with control group, with parallel, double-blind, randomized, phase 3 groups on 52 patients who were randomly divided into two groups of intervention and control, 26 people. In order to randomly assign people to two groups, a random sequence of numbers is created using web-based software.

Settings and conduct

Razi Psychiatric Hospital Double-blind study (patients, researchers, psychiatrists and psychologists, patient caregivers, data collector, data analyst) In addition to treatment with 6 mg risperidone, the intervention group received celecoxib at a dose of 400 mg orally daily (200 mg BD) for 8 weeks, and the control group received a treatment regimen consisting of risperidone tablets with the same placebo. Will receive. Positive, negative and cognitive symptoms of patients will be evaluated when entering the study and then every 2 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Schizophrenic patients in the active phase, Male and female patients ranging in age from 18 to 65 years, Take only one type of antipsychotic drug (risperidone), IQ greater than 70, Having the consent of the patient and his / her guardian to participate in the research Exclusion criteria: Having any debilitating physical illness, Depression based on the Hamilton test, History of gastric ulcer or acute gastric bleeding, Blindness and deafness, Drug, alcohol or drug abuse in the last 6 months (excluding nicotine), Receive ECT in the last two weeks, Breastfeeding and pregnancy

Intervention groups

Patients with schizophrenia are treated with risperidone,

receiving celecoxib as adjunctive therapy, and the control group receiving risperidone and placebo.

Main outcome variables

Positive, negative and cognitive symptoms of schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210831052351N1**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

Registration date

2021-11-16, 1400/08/25

Registrant information

Name

Farahnaz Moradzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of celecoxib as add on to risperidone to reduce positive , negative and cognitive symptoms in schizophrenic patients in active phase: a double-blind, randomized and placebo-controlled clinical trial

Public title

The effect of Celecoxib in the treatment of Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with schizophrenia in the acute phase Age range 18 to 65 years Receiving only one Antipsychotic drug (Risperidone) IQ greater than 70 Having the consent of the patient and his / her guardian to participate in the research

Exclusion criteria:

Having a debilitating physical illness patients with depression Received an electric shock in the last two weeks History of gastric ulcer or acute gastric bleeding Pregnancy and lactation No extra pyramidal symptoms in the study entry based on Simpson-Angus scale Drug, alcohol or drug abuse in the last 6 months (excluding nicotine) There is another diagnosis based on DSM5, including mood disorders and mental retardation Blindness and deafness

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization of software www.sealedenvelope.com/simple-randomiser/v1/lists will be used. Randomization of the unit is done in a block method with a block size of 4. For each of the 6 possible cases for the quadruple block, the numbers are assigned as follows: 2 (ABAB), 1 (AABB), 3 (ABBA), 4 (BBAA), 5 (BABA), 6 (BAAB) With the help of a table of random

numbers, the numbers between 1 and 6 are selected and the treatment allocation list is determined according to each number. To execute the generated random sequence, the method of hiding encoded boxes or cans is used. In this method, the cans are numbered according to a random sequence and inside the boxes, the desired intervention (drug) or a sheet on which the random allocation is written, is provided to the operator with the condition that the boxes are completely sealed. And the researcher assigns them to the standard intervention and treatment group based on the order of patients' admission. Tools: Creating a random sequence of 4 random hiding blocks to execute a random sequence on the study participants. How to make: Randomly select the block and read the letters from right to left. More about this source textSource text required for additional translation information Send feedback Side panels

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants (after obtaining consent) which includes two groups of celecoxib recipients and placebo recipients (with main treatment), project researcher, health care personnel responsible for patient care, a person who examines participants for inclusion and exclusion criteria and enrolls them in the study, The person assigning participants to the groups will be the outcome evaluator, the data analyst will be separate and independent.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the University of Rehabilitation Sciences and Social Health

Street address

Tehran University of Rehabilitation Sciences and Social Health, Evin, Daneshjoo Blvd., Koodkiar dead end

City

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Postal code

1985713834

Approval date

2021-08-30, 1400/06/08

Ethics committee reference number

IR.USWR.REC.1400.135

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Positive symptoms of schizophrenia

Timepoint

Every 2 weeks to 8 weeks

Method of measurement

Positive And Negative Syndrome Scale

2

Description

Negative symptoms of schizophrenia

Timepoint

Every 2 weeks to 8 weeks

Method of measurement

Positive And Negative Syndrome Scale

3

Description

Cognitive symptoms of schizophrenia

Timepoint

Every 2 weeks to 8 weeks

Method of measurement

Montreal Cognitive Assessment Scale

Secondary outcomes

1

Description

Side effects of medications

Timepoint

Every 2 weeks to 8 weeks

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Patients with schizophrenia in the acute phase treated with 6 mg of risperidone manufactured by Abidi Company, which will receive 400 mg of celecoxib (200 mg twice daily) produced in Razak Laboratory for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients with schizophrenia treated with risperidone made by Abidi Company who will receive a placebo similar to celecoxib from Razak Laboratory with magnesium stearate content (capsules, daily dose) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatric hospital

Full name of responsible person

Mahsa Shahbazi

Street address

Shahid Rastegar Blvd., Tehran Varamin Hwy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamid Reza Khorram Khorshid

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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

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Farahnaz Moradzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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