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

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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
Tehran
Province
Tehran
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
City
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1866958891
Phone
+98 21 3340 1220
Email
razi.pr@uswr.ac.ir

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
Street address
University of Social Welfare and Rehabilitation, Kudakyar Alley, Daneshju Blvd, Evin
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Postal code
1985713871
Phone
+98 21 7173 2832
Email
hrkhkh@yahoo.com
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