Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of celecoxib on symptoms of patients with Schizophrenia under Electroconvulsive Therapy

Protocol summary

Study aim

1- Determining the effect of celecoxib compared to placebo on inflammatory indices in patients with schizophrenia treated with electroconvulsive therapy 2- Comparison of inflammatory indicators (blood biochemical changes) in two groups 3- Comparison of overall performance (GAF) in two groups 4- Comparison of cognitive changes in two groups 5- Comparison of changes in positive and negative symptoms (PANSS) in two groups 6- Comparison of possible side effects in two groups

Design

A clinical trial with the control group, with parallel groups, single-blind, randomized, without reference on 48 patients.

Settings and conduct

Schizophrenia patients in Quds Hospital treated with electroconvulsive therapy are randomly divided into witness and control groups. The witness group is given a placebo during the period of receiving electric shocks and the control group is given celecoxib. Inflammatory indices in the blood are measured before and after the procedure and finally, the results are compared.

Participants/Inclusion and exclusion criteria

Schizophrenia patients treated with electric shock with 18 to 60 years old without underlying disease, and not addicted to drugs and alcohol.

Intervention groups

Before the start of the shock therapy sessions, after the third session, and at the end of the sessions, blood samples are taken to check the blood cell count and inflammatory markers. For these patients, the Celecoxib drug is started before the start of shock treatment sessions. Control group: Same as above grout but the direction of these patients starts before the start of the placebo shock therapy sessions.

Main outcome variables

blood biochemical indicators, general performance, cognition, positive and negative symptoms, side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130723014122N2**
Registration date: **2023-04-24, 1402/02/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-24, 1402/02/04**
Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

Azad Maroufi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 1666 0025

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of celecoxib on symptoms of patients with Schizophrenia under Electroconvulsive Therapy

Public title
Effect of celecoxib on symptoms of patients with Schizophrenia under Electroconvulsive Therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with Schizophrenia under Electroconvulsive Therapy
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **3**
Blood sample for testing, blood cell count and inflammatory markers
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, we used the quadruple random block method. For this purpose, we prepare four sheets of paper for each drug and placebo group separately. We write the letter A (intervention group) on two sheets and the letter C (comparison group) on the other two sheets.We mix the sheets together and put them in the desk drawer. With the referral of each of the eligible patients, one of the sheets was randomly drawn and based on this drawn sheet, A or C was assigned to one of the two intervention groups (celecoxib) and the control group (placebo), respectively.It should be noted that the drawn cards are not returned to the drawer until all four cards are drawn. After randomly pulling out fourteen sheets, all the sheets were returned to the drawer and the above operation was continued for the next four patients until the desired sample size was reached.
Blinding (investigator's opinion)
Single blinded
Blinding description
We use the block method for blinding. According to the study, there are 2 modes. State A (Celecoxib drug) State B (Placebo) The order of random placement of these two modes is 6 types. We write these 6 species and assign a number to each one. For example -/1- -/AABB To write the table, we randomly pick a number from among the written numbers and write the state of that number in the table. When the table is filled with the number of participants, we proceed according to the table. For the first participant, we choose the first block, which is, for example, A, and for the second participant, we choose the second block, which is, for example, A again, and move on...
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences
Street address
Pasdaran Ave, Shohadaye Nirooye Entezami Blve., Qods Hspital
City
Sanandaj
Province
Kurdistan
Postal code
6617713141
Approval date
2022-09-13, 1401/06/22
Ethics committee reference number
IR.MUK.REC.1401.418

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood biochemical indicators: CBC diffWBCBaselin monocyte LymphocyteESRCRP
Timepoint
Before the start of shock therapy, the end of the third session and the end of the sessions
Method of measurement
Review of clinical findings

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: celecoxib + ECT and routine drugs, control group: placebo + ECT and routine drugs
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghods hospital in Sanandaj
Full name of responsible person
Dr Azad Maroufi, psychiatrist, professor of Kurdistan University of Medical Sciences
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Shohadaye Niruye Entezami Boulvar,Sanandaj
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Sponsors / Funding sources

1

Sponsor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
empty
Title of funding source
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Sanandaj 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
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Azad Maroufi
Position
Psychiatrist Kurdistan University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Latest degree
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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