

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 group 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

maroufi@muk.ac.ir

##### 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 Niroooye Entezami Blv., 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

#### Street address

Shohadaye Niruye Entezami Boulvar, Sanandaj

#### City

sanandaj

#### Province

Kurdistan

#### Postal code

6617713141

#### Phone

+98 87 3322 9494

#### Fax

+98 87 3323 3600

#### Email

maroufi@muk.ac.ir

#### Street address

Research of Kurdistan University of Medical Sciences

#### City

Sanandaj

#### Province

Kurdistan

#### Postal code

6618634683

#### Phone

+98 87 3322 9494

#### Fax

+98 87 3323 3600

#### Email

info@muk.ac.ir

#### 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

## 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

Azad Maroufi

## 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

#### Street address

Pasdaran street below the Pardis, Ghods hospital,  
Sanandaj

#### City

Sanandaj

#### Province

Kurdistan

#### Postal code

66177\_13446

#### Phone

+98 87 1666 4646

#### Fax

+98 87 1666 4654

#### Email

maroufi@muk.ac.ir

#### Web page address

## Person responsible for scientific 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

**Street address**

Pasdaran street below the Pardis, Ghods hospital,  
Sanandaj

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

66177\_13446

**Phone**

+98 87 1666 4646

**Fax**

+98 87 1666 4654

**Email**

marufi@muk.ac.ir

**Web page address**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Pasdaran street below the Pardis, Ghods hospital,  
Sanandaj

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

66177\_13446

**Phone**

+98 87 1666 4646

**Fax**

+98 87 1666 4654

**Email**

marufi@muk.ac.ir

**Web page address**

## 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

## Person responsible for updating data

### 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**