

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Iranian clozapine versus leponex in the treatment of the positive negative symptoms of schizophrenia: a double-blind randomized crossover trial.

Protocol summary

Summary

The objective of this randomized, double-blind, crossover study is to compare the efficacy of Iranian clozapine (manufactured by Tehran Chemie Pharmaceutical Company, Tehran, Iran) with leponex (manufactured by Novartis Pharmaceutical company- Switzerland) in subjects with schizophrenia. A total of 32 patients with chronic DSM-IV-diagnosed schizophrenia will be randomly assigned into two groups: group A will receive Iranian clozapine during first three months of the study and then will receive leponex for the other three months. Group B will firstly receive leponex and then will receive Iranian clozapine. The patients will be assessed by the Positive and Negative Syndrome Scale (PANSS) at the baseline and after 3 and 6 months after the study starts.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010042935N4**

Registration date: **2010-10-28, 1389/08/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-28, 1389/08/06

Registrant information

Name

Farzin Rezaei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1356 1822

Email address

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2010-07-09, 1389/04/18

Expected recruitment end date

2011-01-08, 1389/10/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Iranian clozapine versus leponex in the treatment of the positive negative symptoms of schizophrenia: a double-blind randomized crossover trial.

Public title

Iranian clozapine versus leponex

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: diagnosis of Schizophrenia based on DSM IV, chronic Schizophrenia, resistant schizophrenia (no response to two different antipsychotics at past)
Exclusion Criteria: Substance dependence, any serious medical problem, development of agranulocytosis or seizure during treatment with clozapine

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of medical Sciences

Street address

Pasdaran Blvd

City

Sanandaj

Postal code

Approval date

2007-12-26, 1386/10/05

Ethics committee reference number

4643

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Severity of schizophrenia

Timepoint

Baseline and 3 and 6 months after beginnig of the treatment

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description

Iranian clozapine (Tehran shimi company) 100 mg TDS for 3 months

Category

Treatment - Drugs

2

Description

leponex (manufactured by Novartis pharmaceutical company-Switzerland) 100 mg tid for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar institute

Full name of responsible person

Dr. Farzin Rezaei

Street address

Baharan district

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ataollah Heydari

Street address

Deputy of research, Kurdistan university of Medical Sciences, Pasdaran Blvd, Sanandaj

City

Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty