

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of efficacy of levetiracetam on cognitive symptoms in schizophrenic patients

Protocol summary

Study aim

To determine the effect of Levetiracetam on cognitive function and quality of life in patients with schizophrenia

Design

40 schizophrenic patients were divided into two groups of intervention and control through block randomization. Randomized, double-blind, placebo-controlled, single-center, phase II trial.

Settings and conduct

The study was conducted at Clinic of Psychiatry of the University Hospital Ibn.e.Sina and Dr. Hejazi, Mashhad. patient was diagnosed with schizophrenia (excluding catatonic schizophrenia subgroups) aged 18-60 years are evaluated based on the inclusion and exclusion criteria (listed below) and only patients who meet these criteria are selected. as a double blind (the patient, elevator and physician a will be blind and the medication and placebo in envelopes A and B will be given by the nurse).

Participants/Inclusion and exclusion criteria

Inclusion criteria; Schizophrenia during partial recovery- Have a normal IQ. do not Be in the acute phase of schizophrenia. haven untreated with clozapine antipsychotic drug. The patient do not take anticholinergic and benzodiazepine medications- Non-pregnant or breastfeeding (Pregnancy Detection Based on BHCG Pregnancy Test).-have not History of drug use in the past 6 months (except nicotine). Exclusion criteria; Lack of consent for participation in the study Serious medical illness

Intervention groups

Intervention group: Levetiracetam (LEV) group, after 2 weeks of antipsychotic treatment, 2-week baseline period at 250 mg LEV dose and increase to maximum LEV dose (500 mg twice daily), and 8-week period intervention will complete. In the placebo group, a placebo that looks similar to levetiracetam is used according to the same protocol.

Main outcome variables

cognitive function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N32**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of levetiracetam on cognitive symptoms in schizophrenic patients

Public title

Evaluation of efficacy of levetiracetam on cognitive symptoms in schizophrenic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

6-month to 10-year history of schizophrenia Have a normal IQ Do not be in the acute phase of schizophrenia. The patient do not take anticholinergic and benzodiazepine medications do not history of drug use in the past 6 months (except nicotine) Do not be pregnant or breastfeeding (Pregnancy Detection Based on BHCG Pregnancy Test)

Exclusion criteria:

Lack of consent for participation in the study Serious medical illness

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly divided into two groups using a random number table. Individuals who receive the odd number enter the intervention group, and people with even numbers are placed in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be assigned to the treatment and control group with a random number table. The nurse will control the drug instruction. The treating physician will examine the patients and be unaware of the intervention. The trial runs in a double-blind manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Qoreishi Building, Daneshgah Street, Mashhad, Iran.

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Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2019-04-09, 1398/01/20

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.231

Health conditions studied

1

Description of health condition studied

schizophrenic

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

cognitive function

Timepoint

At baseline, weeks 4 and 8

Method of measurement

Wisconsin questionnaire, Stroop test

2

Description

Quality of Life

Timepoint

At baseline, weeks 4 and 8

Method of measurement

The Positive and Negative syndrome Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: levetiracetam (LEV) group, after 2 weeks of antipsychotic treatment, 2-week baseline

period at 250 mg LEV dose and increase to maximum LEV dose (500 mg twice daily), and 8-week period intervention will complete.

Category

Treatment - Drugs

2**Description**

Control group: placebo group, a placebo that looks similar to levetiracetam is used according to the same protocol.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ibn.e.Sina Psychiatry Hospital

Full name of responsible person

Dr Fatemeh Behdani

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Ibn-e-Sina Hospita, Bu-Ali Sq., Amel Blvd., Mashhad.

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2**Recruitment center****Name of recruitment center**

Dr Hejazi hospital

Full name of responsible person

Dr Fatemeh Behdani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Behdani

Position

Associated Professor

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Fatemeh Behdani

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available