Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

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+98 51 3711 2540

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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.
City
Mashhad
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

Street address

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

Mashhad 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

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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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