Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of adding pregabalin to antipsychotics on positive and negative symptoms in patients with schizophrenia: A randomized placebo-controlled double blind trial

Protocol summary

Summary

Schizophrenia is a devastating clinical syndrome which deeply affects cognition, emotion, perception and the other aspects of behavior. Antipsychotic agents are not effective in all patients just as on all symptoms of disorder. About 10-20% of schizophrenic patients do not benefit from neuroleptic agents except in small amounts. Therefore, new therapeutic strategies such as neuroleptic combination with anti-epileptic agents have been used to treat the disease. In some cases, prescribing Pregabalin has been reduced anxiety and positive and negative symptoms of schizophrenia. The aim of this study is to investigate the effect of Pregabalin on positive and negative symptoms of refractory schizophrenia. This is a prospective, randomized, double-blind, placebo-controlled study done within 6 weeks. 48 patients were randomly divided into two groups receiving drug and placebo. PANSS, AIMS and Czech list of side effects will be recorded at baseline, week 3 and week 6, by an assistant psychiatry. Pregabalin starts at the doses of 75mg and after three weeks, the dose will be 150 mg. Administration of placebo and increasing the dosage, will be in accordance with Pregabalin. After 6 weeks the data is collected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092711885N7**
Registration date: **2017-01-03, 1395/10/14**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2017-01-03, 1395/10/14

Registrant information

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Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Not enough for processing

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2017-02-03, 1395/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding pregabalin to antipsychotics on positive and negative symptoms in patients with schizophrenia: A randomized placebo-controlled double blind trial

Public title

The effect of pregabalin in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1. Diagnosis of schizophrenia according to DSM-V criteria by psychiatrist 2. Age 18 to 65 years 3. Informed consent / guardian for inclusion 4. Treatment with antipsychotics 5. Refractory schizophrenia Exclusion criteria: 1. Other psychiatric disorders axis I or II exist 2. Serious or chronic diseases like renal and liver dysfunction, severe diarrhea, cardiovascular disease, urinary tract infection, head injury 3. Pregnancy 4. Breastfeeding 5. Lack of appropriate contraception in women of reproductive age 6. Substance abuse over the past month 7. Intolerable side effects 8. History of allergy to Pregabalin 9. Change the doses of antipsychotic agents during last two weeks 10. Patient/ guardian's apply to withdraw from the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciencesnces

Street address
moallem Sq

City
sari

Postal code

Approval date
2016-12-18, 1395/09/28

Ethics committee reference number
IR.MAZUMS.REC.95.1809

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
schizophrenia

Primary outcomes

1

Description
Positive and negative symptom of schizophrenia

Timepoint
Before intervention, three weeks after beginning intervention, the end of intervention

Method of measurement
Positive_and_Negative_Syndrome_Scale

Secondary outcomes

1

Description
Extra pyramidal syndrome

Timepoint
Before intervention, three weeks after beginning intervention, the end of intervention

Method of measurement
Abnormal-Involuntary-Movement-Scale

Intervention groups

1

Description
twenty-four patients receive pregabalin capsule75 mg/ daily up to 3weeks , then twice a day for 3 weeks next

Category
Treatment - Drugs

2

Description
24 patients receive Placebo capsule daily up to 3weeks then twice a day for next 3weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
zare hospital

Full name of responsible person
Dr.samane farnia

Street address
Neka road

City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati MD
Street address
Moallem Square
City
sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mazandaran 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
Name of organization / entity
Medical science of mazandaran university
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Elham mahtiyan
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start of valieasr highway,Imam Sq
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Sm.farnia@gmail.com
Web page address

Person responsible for updating data

Contact

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