

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Name

Samaneh Farnia

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3328 5659

Email address

sfarnia@mazums.ac.ir

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 Sciences

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 capsule 75 mg/ daily up to 3 weeks , then twice a day for 3 weeks next

Category

Treatment - Drugs

2

Description

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

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

Full name of responsible person
Elham mahtiyani

Position
Psychiatrist Assistant

Other areas of specialty/work

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Zare hospital,neka road

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Person responsible for scientific inquiries

Contact

Name of organization / entity
mazandaran university of medical science

Full name of responsible person
Dr samane farnia

Position
Assistant professor

Other areas of specialty/work

Street address
start of valieasr highway,Imam Sq

City
Sari

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+98 11 3328 5659

Fax
Email
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