

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of adding pyridostigmine to second generation antipsychotic drugs on schizophrenia symptoms: A double blind randomised placebo controlled clinical trial

Protocol summary

Summary

In this clinical trial research we select random 30 schizophrenic patients 20-40 years old in psychiatric ward of Golestan hospital that are treated with 2 generation antipsychotic drugs .The main goal of research is checking the effect of adding pyridostigmine with 2 generation antipsychotics on schizophrenia symptoms. after explain about research to patients and their families and filling consent form and with regard to inclusion and exclusion criteria will divide to 2 groups : experimental and placebo groups.we add pyridostigmin tablet 60 mg with experimental group once a day and placebo tablet with control group once a day too.the time of research is 4 weeks.It should be noted that placebo is very similar to pyridostigmine tablets in shape, size, color.we use BPRS and PANSS scales at the beginning and end of research.PANSS scale measure the positive and negative symptoms of schizophrenia and other psychotic disorders and it has become to the standard tool to evaluate the clinical outcome of schizophrenia studies.BPRS is brief scale is used to measure psychiatric symptoms. This scale from a few decades ago is used to assess the outcome of the schizophrenia treatment studies and it is useful for patients with signalize destruction. the main inclusion criteria is having schizophrenia disorder.inclusion criteria : the average age between 20 to 40 years and knowing persian language and having consent of participation in this research and having no brain organic disease and using no any anti depressant such as tricyclics drugs and donepezil drug. exclusion criteria :dementia and severe organic disease and Non-compliance patients and very old age and young age and other neurologic diseases that patients must use anticholinesterase drugs and use of tricyclic antidepressants and donepezil drug. positive symptoms of schizophrenia such as hallucination,dellusion and etc ,negative symptoms such

as abulia and anhedonia and etc,cognitive symptoms such as memory ,attention and etc and agitation and anxiety and depression and duration of hospitalization are main outcome variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041521779N1**

Registration date: **2015-10-28, 1394/08/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-28, 1394/08/06

Registrant information

Name

Rokhshid Pirboveri

Name of organization / entity

Jondi Shapour university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Jondi Shapour university of medical sciences of Ahvaz

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2016-06-01, 1395/03/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
The effect of adding pyridostigmine to second generation antipsychotic drugs on schizophrenia symptoms: A double blind randomised placebo controlled clinical trial

Public title
The effect of adding pyridostigmine to second generation antipsychotic drugs on schizophrenia symptoms: A double blind randomised placebo controlled clinical trial

Purpose
Treatment
Inclusion/Exclusion criteria
The main inclusion criteria is having schizophrenia disorder.inclusion criteria: The average age between 20 to 40 years and knowing persian language and having consent of participation in this research and having no brain organic disease and using no any anti depressants such as tricyclics drugs and donepezi drug. Exclusion criteria :demensia and severe organic disease and very old age and young age and other neurologic diseases that patients must use anticholinesterase drugs and use of tricyclic antidepressants and donepezil drug.

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

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 Committy of Jondi Shapour University of Medical Sciences of Ahvaz
Street address
Golestan Street, Ahvaz , Khouzestan
City
Ahvaz
Postal code
6135874366
Approval date
2015-01-31, 1393/11/11
Ethics committee reference number
13930401

Health conditions studied

1
Description of health condition studied
Schizophrenia
ICD-10 code
f20

ICD-10 code description
The schizophrenic disorders are characterized in general by fundamental and characteristic distortions of thinking and perception, and affects that are inappropriate or blunted. Clear consciousness and intellectual capacity are usually maintained although

Primary outcomes

1
Description
Schizophrenic Disorder Symptom
Timepoint
In First And End Of 4 Weeks Of Research
Method of measurement
By Using Panss And Bprs Scales

Secondary outcomes

1
Description
Comparision between complications of adding pyridostigmine with 2 generation antipsycotic drugs versus complications of antipsychotics alone
Timepoint
Along of research
Method of measurement
With recurrent visit of patients.

Intervention groups

1
Description
Interventional group:this group that include 15 schizophrenic patients are selected quite rondon and treated with 2 generation antipsychotic drugs , pyridostigmine tablet 60 mg will add to main treatment

daily for one month. It is worth mentioning that pyridostigmine is one of anticholinesterase drugs and one of common treatment of MYASTHENIA GRAVIS disease. At the beginning and end of 4 weeks we check PANSS and BPRS for patients.

Category

Treatment - Drugs

2**Description**

In placebo group that include 15 schizophrenic patients are selected random and treated with 2 generation antipsychotic drugs, placebo tablet that is quite similar to pyridostigmine tablet will add to their main treatment for one month. At beginning and end of 4 weeks, PANSS and BPRS scales will check for patients.

Category

Treatment - Drugs

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

Golestan Hospital of Ahvaz

Full name of responsible person

Dr Boostani Haatam, Assistant Professor of Psychiatry of Jondi Shapour University of Medical Sciences

Street address

Golestan Hospital, Golestan Street, Ahvaz

City

Ahvaz

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

Vice Chancellor for Research of Jondi Shapour University of Medical Sciences of Ahvaz

Full name of responsible person

Dr Saaki Naader

Street address

Jondi Shapour University of Medical Sciences of Ahvaz, Golestan Street, Ahvaz, Khuzestan

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Ahvaz

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 of Jondi Shapour University of Medical Sciences of Ahvaz

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**

Jondi Shapour University of Medical Sciences of Ahvaz

Full name of responsible person

Dr Pakseresht Syrous

Position

Assistant Professor of Psychiatry in Jondi Shapour University of Medical Sciences of Ahvaz

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Full name of responsible person

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Other areas of specialty/work**Street address**

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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