Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation the Effect of Adding Galantamine to Second Generation Antipsychotics, on Negative Symptoms of Schizophrenia

Protocol summary

Study aim
Evaluation the Effect of Adding Galantamine to Second Generation Antipsychotics, on Negative Symptoms of Schizophrenia

Design
A clinical trial with a community-based and pragmatic control group with randomized blocking , double-blind and consisting of 28 patients with schizophrenia

Settings and conduct
Patients are divided into two groups according to the permutation block method.the placebo is similar to Galantamin in shape, color, smell, and taste and will be available at the Faculty of Pharmacy, Ahwaz University of Medical Sciences. The medication will be prescribed by the assistants and given to the patients by the nurses at a psychiatric ward. The project executor is not aware of the prescriptions in each group. Also, patients are unaware of their treatment

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of schizophrenia based on the DSM-5, Age of 18-55 years, Get at least one second-generation anti-psychotic drug within the dose range, Having a score of at least 15 in the subgroup of negative marks on the PANSS assessment scale. Exclusion Criteria: Other disorders in axis 1, The presence of disorders like cardiac disease , liver disease , kidney disease and etc, History of allergy to second-generation antipsychotics, Positive test for amphetamines or methamphetamines , Pregnancy or breastfeeding, Concomitant treatment with anticholinergic drugs, The existence of suicidal thought

Intervention groups
Intervention group: In the case group, initially, prescribing gallantamine will begin with a dose of 4 mg twice daily, which will gradually be increased to 12 mg twice a day over a period of four weeks and will continue until the end of week 8 Control group: This group will receive placebo which is similar to Galantamin in shape, color, smell, and taste.

Main outcome variables
Negative sign of Schizophrenia

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181117041682N2**
Registration date: **2019-03-10, 1397/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-10, 1397/12/19**
Update count: **0**

Registration date
2019-03-10, 1397/12/19

Registrant information
Name
Ahmad Fakhri
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3622 4558
Email address
ahmad_fakhri@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-01-21, 1397/11/01
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the Effect of Adding Galantamine to Second Generation Antipsychotics, on Negative Symptoms of Schizophrenia

Public title
Evaluation the Effect of Adding Galantamine to Second Generation Antipsychotics

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of schizophrenia based on the DSM-5 Age of 18-55 years Get at least one second-generation anti-psychotic drug within the dose range Having a score of at least 15 in the subgroup of negative marks on the PANSS assessment scale

Exclusion criteria:
Other disorders in axis 1 The presence of cardiac disorders, liver disorders, kidney disorders and etc. History of allergy to second-generation antipsychotics Positive test for amphetamines or methamphetamines at initiate time of admission Pregnancy or breastfeeding Simultaneous treatment with anticholinergic drugs The existence of suicidal thoughts

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the method of the permutation blocks of size 4, individuals are randomly divided into two groups. Samples will be divided into two experimental and control groups based on permutation blocks (blocks of size 4). It will be listed according to six possible ways (AABB, ABAB, ...) randomly and the arrangement of receiving intervention will be determined accordingly.

Blinding (investigator's opinion)
Double blinded

Blinding description
the placebo is similar to Galantamin in shape, color, smell, and taste and will be available at the Faculty of Pharmacy, Ahwaz University of Medical Sciences. The medication will be prescribed by the assistants and given to the patients by the nurses at a psychiatric ward. The project executor is not aware of the prescriptions in each group. Also, patients are unaware of their treatment

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan Blvd, Ahvaz, Khoozestan

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2018-11-27, 1397/09/06

Ethics committee reference number
IR.AJUMS.REC.1397.634

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Negative sign of Schizophrenia

Timepoint
at the start of treatment, weeks 2, 4 and 8 of treatment

Method of measurement
Oveall scale score PANS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the case group in addition use of second-generation anti-psychoactive agent Galantamin

is added. initially, prescribing gallantamine will begin with a dose of 4 mg twice daily, which will gradually be increased to 12 mg twice a day over a period of four weeks and will continue until the end of week 8. .

Category

Treatment - Drugs

2

Description

Control group: More over receiving second-generation anti-psychoactive agent, also placebo is added. Placebo is a pill that looks like Galantamine in terms of its shape, color, smell and taste.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Psychiatry Clinic, Golestan Hospital

Full name of responsible person
Ahmad Fakhri

Street address
Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3374 3038

Email
ahmad_fakhri@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad Badavi

Street address
Ahvaz Junishapur University of Medical Science,Farvardin Blvd

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3374 3038

Email
badavi.m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Ahmad Fakhri

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3374 3038

Email
Dr.fakhri@gmil.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Zahra Roshandel

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz

City
Ahvaz

Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3038
Email
roshandelzahra@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zahra Roshandel
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3038
Email
roshandelzahra@yahoo.com

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
No more 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
No - There is not a plan to make this available