Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Efficacy of Rivastigmine Augementation to Antipsychotic Agents on Positive and Negative Symptoms and Quality of Life in Patients with Chronic Schizophrenia

Protocol summary

Study aim

The effect of adding Rivastigmine to antipsychotic medications, regarding the positive and negative symptoms of life among the patients of chronic schizophrenia

Design

People hospitalized because of chronic Schizophrenia in Razi Hospital of Tabriz form the statistical population. 60 patients will be selected as the sample of study, in a totally blind way. they will be divided into rivastigmine and placebo groups, randomly. The rivastigmine group will receive antipsychotic and Rivastigmine in 8 weeks; at the same time, the placebo group will receive placebo.

Settings and conduct

The patients hospitalized for chronic Schizophrenia in Razi Hospital of Tabriz will be studied; the study is double blind; and rivastigmine and placebo groups, will be formed randomly. The rivastigmine group will receive antipsychotic and Rivastigmine in 8 weeks; at the same time, the placebo group will receive placebo. The participants will be assessed at the start of study, at the end of 4th week and at the end of study.

Participants/Inclusion and exclusion criteria

The patients hospitalized for Schizophrenia who were medicated with antipsychotic are eligible to enter the statistical population of this study. People with the following requirements will be removed from the list: drug abuse, IQ less than 70, other psychotic disorders, medical diseases, allergy to Rivastigmine, and people who had received ECT during the last 2 weeks.

Intervention groups

The rivastigmine group will receive antipsychotic and Rivastigmine in eight weeks; at the same time, the placebo group will receive placebo.

Main outcome variables

Important outcomes of this disease are decreased performance, social isolation, increased hospitalization times and mortality. The quality of life is one of the important criteria that determines the effects of Schizophrenia and its therapy on a patient.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190530043769N1**
Registration date: **2021-01-26, 1399/11/07**
Registration timing: **prospective**

Last update: **2021-01-26, 1399/11/07**
Update count: **0**

Registration date

2021-01-26, 1399/11/07

Registrant information

Name

Zahra Jahangiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3667 1359

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy of Rivastigmine Augementation to Antipsychotic Agents on Positive and Negative Symptoms and Quality of Life in Patients with Chronic Schizophrenia

Public title
The Efficacy of Rivastigmine Augementation to Antipsychotic Agents on Positive and Negative Symptoms and Quality of Life in Patients with Chronic Schizophrenia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with Chronic Schizophrenia Patients treated with Antipsychotics
Exclusion criteria:
Drug abuse IQ less than 70 Another psychiatric disorder Physical illness ECT in the last two weeks Sensitivity to Rivastigmine
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blind: Participants, Patient care, The responsible person for gathering data, Hospital staff, Data analyzer
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz Razi Hospital, Sheikh Mohammad KHiyabani Blvd, Elgoli, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5167846184
Approval date
2021-01-10, 1399/10/21
Ethics committee reference number
IR.TBZMED.REC.1399.923

Health conditions studied

1

Description of health condition studied
Chronic schizophrenia
ICD-10 code
F20.0
ICD-10 code description
Paranoid schizophrenia

Primary outcomes

1

Description
Efficacy of Rivastigmine
Timepoint
Efficacy of Rivastigmine in three stages: at the start point, after 4 weeks and at the end of study
Method of measurement
Positive, negative symptoms questionnaire in Chronic schizophrenia patients

2

Description
Efficacy of rivastigmine
Timepoint
Efficacy of Rivastigmine in three stages: at the start point, after 4 weeks and at the end of study
Method of measurement
Quality of Life Questionnaire in Chronic schizophrenic Patients

Secondary outcomes

1

Description
Side effect
Timepoint

Two months after starting therapy

Method of measurement

Medical history and examination

Intervention groups

1

Description

Interference Group: this group includes chronic schizophrenia patients that receive Rivastigmine capsules (1.5 mg) twice daily along with the previous antipsychotic medication for eight weeks. The medication is produced in Razak factory. Patients will be examined daily regarding the side effects of medication. They will be assessed in three stages; at the start point, after four weeks and at the end of eight weeks, using PANSS questionnaires and life quality.

Category

Treatment - Drugs

2

Description

Control group: this group includes chronic schizophrenia patients that receive placebo twice daily along with the previous antipsychotic medication for eight weeks. Patients will be examined daily regarding the side effects of medication. They will be assessed in three stages; at the start point, after four weeks and at the end of eight weeks, using PANSS questionnaires and life quality.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Razi Hospital

Full name of responsible person

Sepideh Herizchi Ghadim

Street address

Tabriz Razi Hospital, Sheikh Mohammad KHiyabani Blvd, Elgoli, Tabriz

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Sponsors / Funding sources

1

Sponsor

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Jahangiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After the clinical study, statistical tests and acquiring the results, the entire stages of study, including: history, method, discussion and conclusion will be shared as thesis and articles in the reputable and relevant journals.
When the data will become available and for how long
After being approved by supervisor, advisor and Referees, the thesis will be shared according the norms of Tabriz University of Medical Sciences.
To whom data/document is available
Thesis will be shared according to the norms of library to Tabriz University of Medical Sciences; also, the article will be shared according to the norms of journals.
Under which criteria data/document could be used
The documents will be available according to the norms of university and journals, in order for the scientific community to be aware of the scientific results of this study.
From where data/document is obtainable
To receive the documents please refer the library of Tabriz University of Medical Sciences.
What processes are involved for a request to access data/document
According to the approved stages of Tabriz University of Medical Sciences.
Comments