

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Efficacy of Rivastigmine Augmentation 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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za.jahangiri1986@gmail.com

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 Augmentation to Antipsychotic Agents on Positive and Negative Symptoms and Quality of Life in Patients with Chronic Schizophrenia

Public title

The Efficacy of Rivastigmine Augmentation 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

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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

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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