

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The study of the efficacy of rivastigmin in cognitive status of schizophrenic patients

Protocol summary

Summary

Schizophrenia, as a major psychiatric disorder is very often associated with cognitive impairments. These impairments include deficits in the process of thinking, attention-precaution, memory function, memory and verbal learning, memory and visual learning, logic and problem solving, and verbal perception. These deficits may lead to reduced social and somatic functions. Of importance is to note to these problems in any treatment programming. Many authors believed that acethyl cholin may play an important role in cognitive processes in human brain and that the reduction of acethyl cholin may result in at least a couple of cognitive symptoms in schizophrenic patients. Rivastigmin, a cholin esterase inhibitor, is an agent which is used in clinical trials aimed at resolving cognitive symptoms. This study is designed to examine the efficacy of rivastigmin in treatment of cognitive symptoms in schizophrenic patients. This is an experimental single-blind study. 30 schizophrenic patients, under treatment with atypical antipsychotic medications are divided in two 15-persons groups. The subject group will receive rivastigmin plus antipsychotics, and the control group will receive placebo and antipsychotics. MMSE questionnaire will be used to detect cognitive skills in both groups at two stages: 1) at the beginning of the study, and 2) at 12 weeks later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110083010N3**

Registration date: **2012-01-01, 1390/10/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-01, 1390/10/11

Registrant information

Name

Faeze Tatari

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 4618

Email address

ftatari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-05-04, 1391/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the efficacy of rivastigmin in cognitive status of schizophrenic patients

Public title

The study of the efficacy of rivastigmin in cognitive status of schizophrenic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusive criteria: 1) the diagnosis of schizophrenia made

by the psychiatrist based on DSM.IV.TR; 1) the presence of some cognitive deficits; 3) being volunteer to participate in the study; 4) being under treatment with atypical antipsychotic medications. Exclusion criteria: 1) disagreement to participate in the study; 2) treatment with typical antipsychotic agents; 3) absence of any of inclusive criteria; 4) concordance of substance dependence disorders; 5) co-morbidity with organic mental disorders.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Kermanshah University of Medical Sciences and Health Services

Street address

Vice chancellor for research, Kermanshah University of Medical Sciences and Health Services, building no. 2, Shahid Beheshti blvd.

City

Kermanshah

Postal code**Approval date**

2011-09-23, 1390/07/01

Ethics committee reference number

پ/ن/۴۲

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20-F29

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

Primary outcomes**1****Description**

Cognitive status

Timepoint

The week 0 and week 12

Method of measurement

MMSE questionnaire

Secondary outcomes**1****Description**

Improvement of cognitive status

Timepoint

The weeks 0 and 12

Method of measurement

MMSE questionnaire

Intervention groups**1****Description**

Additive treatment with rivastigmin in intervention group, Rivastigmin 1.5 to 6 mg/ day in one to divided doses.

Category

Treatment - Drugs

2**Description**

Addition of placebo instead of rivastigmin in control group

Category

Placebo

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

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Fazeh Tatari

Street address

Farabi Hospital, Ashayer Sqare.

City

Kermanshh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Farid Najafi

Street address

Kermanshah University of Medical Sciences, building no.2, Shahid Beheshti blvd

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences and Health Services

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**

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Faezeh Tatari

Position

Psychiatrist/Assistant professor

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

Farabi Hospital, Ashayer Square.

City

Kermanshah

Postal code**Phone**

+98 83 1826 0700

Fax**Email**

ftatari@kums.ac.ir , fztatari@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Faezeh Tatari

Position

Psychiatrist/assistant professor

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

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Fax**Email**

ftatari@kums.ac.ir , fztatari@yahoo.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