Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of Rivastigmine on reducing the symptoms of Tardive dyskinesia in patients with Schizophrenia

Protocol summary

Summary

(1)Objectives. The aim of this study was to examine the effects of Rivastigmine on Tardive dyskinesia in patients with schizophrenia. (2) Design. by chance, double blind, control with placebo (3) Setting and conduct. 40 schizophrenic patients (DSM IV-TR) who were hospitalized in Razi hospital were divided in two equal groups by chance. Then one group was taken Rivastigmine and the other one placebo in a double blind method. At the beginning and at the end of study (8 weeks) the patients were assessed by Abnormal Involuntary Movement Scale (AIMS). The results were analyzed with covariance method. (4) Participants including major eligibility criteria. 40 schizophrenic patients (DSM IV-TR) who were hospitalized in Razi hospital and had stable mental status and general medical conditions were divided in two equal groups by chance. (with age range between 18 to 65 years). (5)Intervention. One group was taken Rivastigmine and the other one placebo in a double blind method. (6) main outcome measures (variables). Primary outcome measure: Tardive dyskinesia symptoms Primary outcome time point: At baseline and after eight weeks follow-up Primary outcome method of measurement: Abnormal Involuntary Movement Scale (AIMS)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092910964N1**
Registration date: **2013-01-08, 1391/10/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-08, 1391/10/19

Registrant information

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Amirabbas Jahanian
Name of organization / entity
University of Social Welfare and Rehabilitation Sciences
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Iran (Islamic Republic of)
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amirabbasjahanian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-02-04, 1390/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Rivastigmine on reducing the symptoms of Tardive dyskinesia in patients with Schizophrenia

Public title

The effectiveness of Rivastigmine on treatment of Tardive dyskinesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age range between 18 to 65 years, Spent at least one year of treatment with antipsychotics,

to have a stable condition of the patient for at least one month prior to study entry. Exclusion criteria: Organic brain disease, Any neurological disorders, Having a chronic health problem, Change in the amount or type of antipsychotic medication or tranquilizers were used during the last 6 months so that might affect the patient's motor symptoms, Patients with mental retardation, Patients with thyroid disorders, Diabetes, and Substance Abusers.

Age
From **18 years** old to **65 years** old

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

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 committee of University of Social Welfare and Rehabilitation

Street address
University of Social Welfare and Rehabilitation, Koodakyar str.,Daneshjoo blvd.,Evin str., Tehran.

City
Tehran

Postal code
1985713834

Approval date
2011-04-21, 1390/02/01

Ethics committee reference number
900148

Health conditions studied

1

Description of health condition studied
Tardive dyskinesia

ICD-10 code
G24.0

ICD-10 code description
Drug-induced dystonia

Primary outcomes

1

Description
Tardive dyskinesia symptoms

Timepoint
At baseline and after eight weeks follow-up

Method of measurement
Abnormal Involuntary Movement Scale (AIMS)

Secondary outcomes

empty

Intervention groups

1

Description
in intervention group: Rivastigmine,1.5 mg capsules, twice a day, in 4 weeks.

Category
Treatment - Drugs

2

Description
in control group: sugar,1.5 mg capsules, twice a day, in 4 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Dr. Amirabbas Jahanian

Street address
Razi hospital, Amin abad, Shahr rey.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Vice chancellor for research, University of Social

Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar str., Daneshjoo blvd., Evin str., Tehran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Social Welfare and Rehabilitation Sciences

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

University of Social Welfare and Rehabilitation

Full name of responsible person

Dr.Amirabbas Jahanian

Position

psychiatric / board

Other areas of specialty/work

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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