

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The comparison effect of memantin in improvement of quality of life and global function in patients with schizophrenia

Protocol summary

Summary

This study is clinical trial double blind (patients and researcher) placebo control that evaluate the efficacy of memantine in treatment of schizophrenia. Criteria for inclusion: age group 18-65 years old; no pregnancy or milking; no mental retardation. Criteria for exclusion: allergy to memantine; drug or substance abuse or dependency. 64 patients with schizophrenia divided into two groups: intervention and control. Both of 2 groups receive one atypical anti psychotic, in addition patients in intervention group receive memantin and in control group receive placebo. In intervention group, memantin start with 5mg per day, and its dose increases 5mg weekly, after 4 weeks, it will be 20 mg per day. Clinical assessment perform in baseline and each 4 weeks to 12 weeks, using positive and negative syndrome scale (PANSS), Quality Of Life Scale (QLS), Global Assessment Of Functioning (GAF), Calgary Depressive Scale for Schizophrenia (CDSS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092819320N1**

Registration date: **2014-11-01, 1393/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-01, 1393/08/10

Registrant information

Name

Maryam Mohammadian Sichani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3335 9467

Email address

farshid5@sepahan.iut.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Isfahan University of Medical science

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2014-03-11, 1392/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of memantin in improvement of quality of life and global function in patients with schizophrenia

Public title

Effect of memantin in treatment of patients with schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age group 18-65 ; no mental retardation ; no pregnancy or milking ; diagnosis of schizophrenia for at least 2 years; treatment with atypical anti psychotic from 3 month ago; do not have ECT during 2 week ago
Exclusion criteria: allergic to memantin; addiction or dependency to substance or drugs ; other psychiatric disorder or serious neurological deficit.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Science, Aven Hezar Jerib 9, Isfahan, IRAN

City

Isfahan

Postal code**Approval date**

2013-05-29, 1392/03/08

Ethics committee reference number

392220

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

schizophrenia

ICD-10 code

F20, F21, F2

ICD-10 code description

Schizophrenia, schizotypal and delusional disorder

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

Quality of life

Timepoint

at base line, each 4 weeks to 12 weeks

Method of measurement

Quality Of Life scale of schizophrenia

2**Description**

Global Function

Timepoint

at baseline, each 4 weeks to 12 weeks

Method of measurement

Global Assessment Of Functioning

3**Description**

Positive and negative symptoms

Timepoint

at base line, each 4 weeks to 12 weeks

Method of measurement

Positive And Negative Symptom Scale

4**Description**

Depression

Timepoint

at base line, each 4 weeks to 12 weeks

Method of measurement

Calgary Depressive Scale for Schizophrenia

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

side effects

Timepoint

during 12 weeks of study

Method of measurement

history of patient and his/her companion and physical exam

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

control group: placebo tablet that is similar to memantin in shape, size and color. starting with single dose 5mg per day then increase 5mg each week, up to 10 mg at morning and 10 mg at night after 4 weeks and continuation (10 mg BD) to 12 weeks.

Category

Placebo

2**Description**

study group: memantine tab, starting with single dose

5mg per day then increase 5mg each week ,up to 10 mg at morning and 10 mg at night after 4 weeks and continue (10 mg BD)to12 weeks.

Category

Treatment - Drugs

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

Noor Hospital

Full name of responsible person

Mohammadian Sichani Maryam

Street address

Noor Hospital, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Isfahan University of Medical science

Full name of responsible person

Dr Ciavash,Manager of Vice chancellor for research of Isfahan University of Medical science

Street address

Isfahan University of Medical Science,Avenue HezarJerib, Isfahan, Iran

City

Isfahan

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

Yes

Title of funding source

Vice chancellor for research of Isfahan University of Medical science

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**

Isfahan University of Medical Sciences

Full name of responsible person

Mohammadian Sichani Maryam

Position

Resident of Psychiatric

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

University of medical Sciences, avenue Hezar jeribe, Isfahan, Iran

City

Isfahan

Postal code**Phone**

+98 31 3222 2475

Fax**Email**

farshid5@sepahan.iut.ac.ir;

Mohammadian99@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Science

Full name of responsible person

Mohammadian Sichani Maryam

Position

Resident of psychiatric

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

University of Medical Science, Avenue Hezar jerib, Isfahan, Iran

City

Isfahan

Postal code**Phone**

+98 31 3222 2475

Fax**Email**

farshid5@sepahan.iut.ac.ir ;

Mohammadian99@Yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Mohammadian Sichani Maryam

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Resident of Psychitric

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

Isfahan

Postal code**Phone**

+98 31 3222 2475

Fax**Email**

farshid5@sepahan.iut.ac.ir;

Mohammadian99@Yahoo.com

Web page address

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