

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Efficacy of Memantine as an Adjuvant Therapy in Bipolar Disorder

Protocol summary

Summary

The aim of the present study is to assess the efficacy of memantine as an adjuvant agent in the treatment of bipolar disorder (mania episode) in a six-week double-blind, placebo controlled trial. 40 patients with mania hospitalized in Qods Hospitals who meet inclusion criteria will participate in the trial. Patients will be randomly allocated into two groups. The first group (20 patients) will receive lithium carbonate (1-1/2 meq/lit) + Risperidone 2-6 mg/day plus memantine 20 mg/day (10 mg bid); the second group (20 patients) will receive lithium carbonate (1-1/2 meq/lit) + Risperidone 2-6 mg/day plus placebo. Severity of mania and extrapyramidal side effects will be assessed by Young Mania Rating Scale and Extrapyramidal Symptoms Rating Scale (ESRS) at baseline and after 1, 2, 4 and 6 weeks after the trial started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091514676N1**

Registration date: **2013-12-01, 1392/09/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-01, 1392/09/10

Registrant information

Name

Shahab Bahrami

Name of organization / entity

Kurdistan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Memantine as an Adjuvant Therapy in Bipolar Disorder

Public title

Efficacy of Memantine in bipolar

Purpose

Treatment

Inclusion/Exclusion criteria

This study is performed on patients between the years 2013 to 2014 at Qods Hospital in Sanandaj admitted with a diagnosis of bipolar I disorder in acute mania phase. Inclusion criteria: history of bipolar disorder (manic acute phase), with or without psychotic symptoms according to DSM-IV-TR clinical interview by a psychiatrist; earn at least 20 points YMRS mania that has revealed; age 18 to 60 years old; obtaining informed consent from a parent or legal guardian of the patient; living in Sanandaj, Iran. Exclusion criteria: Alcohol and drug dependence or abuse during the 3 months prior to admission (excluding nicotine or caffeine); psychiatric disorders on Axis II (according to DSM-IV-TR), which can interfere with the study; delirium, dementia and cognitive disorders; Schizophrenia, schizoaffective

disorder, and psychotic disorders; evidence of heart disease, kidney disease, liver disease (based on medical records) that may cause difficulty in the study; pregnancy and lactation; mental retardation based on clinical assessment, the therapist; history of drug allergy or adverse drug with risperidone and lithium carbonate or Memantine; any history of seizure; Memantine use of the 3 months prior to admission.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

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

Kurdistan University of Medical Sciences

Street address

Pasdaran BLV , Pardis of University Sanandaj
Kurdistan Iran, Islamic Republic Of

City

Sanandaj

Postal code

66177-13446

Approval date

2013-09-25, 1392/07/03

Ethics committee reference number

14/22988

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

Primary outcomes

1

Description

Severity of mania

Timepoint

Baseline and weerks 1, 2, 4, 6

Method of measurement

By Young Mania Rating Scale

Secondary outcomes

1

Description

Severity of extrapyramidal side effects

Timepoint

weerks 1, 2, 4, 6

Method of measurement

By Extrapyramidal Symptom Rating Scale(ESRS)

Intervention groups

1

Description

Intervention group:tab lithium
carbonate300mg(1-1/2meq/lit) + Risperidone2-6 mg/day
+ memantine20 mg/day (10 mg bid)

Category

Treatment - Drugs

2

Description

Intervention group:tab lithium
carbonate300mg(1-1/2meq/lit) + Risperidone2-6 mg/day
+placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods Hospital

Full name of responsible person

Dr. Shahab Bahrami

Street address

Qods hospital, Pasdaran Blvd., Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ataollah Heydari

Street address

Pasdarán Blvd, Kurdistan University of Medical Sciences, Deputy of research, Sanandaj

City

Sanandaj

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, Kurdistan University of Medical 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**

Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Shahab Bahrami

Position

MD, resident of psychiatry

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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