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 patient 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(1-1/2meq/lit) + Risperidone2-6 mg/day plus memantine20 mg/day (10 mg bid); the second group(20 patients) will receive lithium carbonate(1-1/2meq/lit) + Risperidone2-6 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 after1, 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
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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 years2013 to2014 at Qods Hospital in Sanandaj admitted with a diagnosis of bipolar1 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, Irann. 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 hospiatal, 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
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Pasdaran 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

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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