Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Evaluating the Effectiveness of Memantine as Adjuvant Treatment on the Symptoms of Acute Mania in the Patients with Bipolar 1 Disorder

Protocol summary

Summary

Objectives: Evaluate the Effectiveness of Memantine as Adjuvant Treatment on the Symptoms of Acute Mania in the Patients with Bipolar 1 Disorder. Design: This study is a double-blind with non-randomized sampling method. A total of 90 patients were chosen with bipolar mania that referred to Amir Kabir Hospital. They Sequentially will divide into intervention (n=45) and control (n=45) groups. The intervention group will receive 20 to 30 mg memantine per day, 20 to 30 mg per kg valproate sodium per day and 10 to 25 mg olanzapine per day. Also, the control group will receive placebo, 20 to 30 mg per kg valproate sodium per day and 10 to 25 mg olanzapine per day. Study will perform during the eight weeks and patients will be put under evaluation by Young Mania Rating Scale at the beginning of the study, second week, fourth week and eighth week. Inclusion criteria: Between 18 to 60 years old; Meet the criteria for bipolar disorder based on DSM-1V-TR diagnostic criteria and clinical interview by a psychiatrist; Existence of mania, with a minimum score of 20 in Young Mania Rating Scale; Lack of psychiatric diseases; Without mental retardation; Lack of any disease that make a problem in the clinical study; Do not consume narcotic, stimulants and alcohol except nicotine in the three last months; Do not electroconvulsive therapy in the previous month; Not pregnant; Without drug allergy and drug side effects history on the this study drugs; Do not consume memantine in the three last months; Lack of dementia, delirium, cognitive disorders and epilepsy. Exclusion criteria: Drugs side effect that causing discontinuation of consume them; Request by the patient or the patient's parent or legal guardian to withdraw from the study at any time of the study; Consume of alcohol or narcotic by the patient after starting the study; Lack of response to the drug therapy after 2 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121725031N6**
Registration date: **2017-01-30, 1395/11/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-30, 1395/11/11

Registrant information

Name
Fatemeh Rafiei
Name of organization / entity
Arak University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 86 3226 5732
Email address
a.rafiei@tafreshu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the Effectiveness of Memantine as Adjuvant Treatment on the Symptoms of Acute Mania in the Patients with Bipolar 1 Disorder

Public title
Evaluating the Effectiveness of Memantine on the Symptoms of Acute Mania in the Patients with Bipolar 1 Disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Between 18 to 60 years old; Meet the criteria for bipolar disorder based on DSM-1V-TR diagnostic criteria and clinical interview by a psychiatrist; Existence of mania, with a minimum score of 20 in Young Mania Rating Scale; Lack of psychiatric diseases; Without mental retardation; Lack of any disease that make a problem in the clinical study; Do not consume narcotic, stimulants and alcohol except nicotine in the three last months; Do not electroconvulsive therapy in the previous month; Not pregnant; Without drug allergy and drug side effects history on the this study drugs; Do not consume memantine in the three last months; Lack of dementia, delirium, cognitive disorders and epilepsy. Exclusion criteria: Drugs side effect that causing discontinuation of consume them; Request by the patient or the patient's parent or legal guardian to withdraw from the study at any time of the study; Consume of alcohol or narcotic by the patient after starting the study; Lack of response to the drug therapy after 2 weeks.

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: **90**

Randomization (investigator's opinion)
Not 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 Committe of Arak University of Medical Sciences

Street address
Basij Square, Sardasht, Arak, Iran

City
Arak

Postal code

Approval date
2014-05-05, 1393/02/15

Ethics committee reference number
93-162-14

Health conditions studied

1

Description of health condition studied
Bipolar I disorder

ICD-10 code
F31.0

ICD-10 code description
Bipolar affective disorder, current episode hypomanic

Primary outcomes

1

Description
Clinical symptoms of mania

Timepoint
At the beginning of treatment, second week, forth week and eighth week.

Method of measurement
Young Mania Rating Scale Measure

Secondary outcomes

empty

Intervention groups

1

Description
Placebo capsule, once a day will start at the baseline and after 3 days will increase to twice a day. In the sixth day, placebo dose will increase to 3 times a day and will continue with same dose until eighth week. Also, valproate sodium 20 to 30 mg and olanzapine 10 to 25 mg once a day will start at the baseline and will continue with same dose until eighth week.

Category
Placebo

2

Description
Memantine 10 mg capsule, once a day will start at the baseline and after 3 days will increase to twice a day. In the sixth day, memantine dose will increase to 3 times a day and will continue with the same dose until eighth

week. Also, valproate sodium 20 to 30 mg and olanzapine 10 to 25 mg once a day will start at the baseline and will continue with same dose until eighth week.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir Hospital
Full name of responsible person
Dr. Alireza Rafiei
Street address
Amir-Kabir Hospital, Parastar Square, Arak, Iran
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Rafiei
Street address
Amir-al-Momenin Hospital, Basij Square, Sardasht, Arak, Iran
City
Arak
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 Arak 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
Amir Kabir Hospital
Full name of responsible person
Dr. Alireza Rafiei
Position
Professional Doctorates, Psychiatry Assistant
Other areas of specialty/work
Street address
Amir-Kabir Hospital, Parastar Square, Arak, Iran
City
Arak
Postal code
3848176941
Phone
+98 863313471519
Fax
Email
rafieidr93@gmail.com; rafiei90dr@yahoo.com; rafiei93dr@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Alireza Rafiei
Position
Professional Doctorates, Psychiatry Assistant
Other areas of specialty/work
Street address
Shahid Zolfaghari Alley, Imam Hossein Street, Hepko Street, Arak, Markazi, Iran
City
Arak
Postal code
3817994813
Phone
+98 863313471519
Fax
Email
rafiei93dr@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Science
Full name of responsible person
Dr. Alireza Rafiei
Position
Professional Doctorates, Psychiatry Assistant
Other areas of specialty/work
Street address
Shahid Zolfaghari Alley, Imam Hossein Street, Hepko Street, Arak, Markazi, Iran
City
Arak
Postal code
Phone

+98 863313471519

Fax

Email

rafiei93dr@gmail.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