

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Comparison of Adjunctive Quetiapine Versus Adjunctive Haloperidol in Combination with Sodium Valproate for Treatment of Patients with Mania or Mixed Feature Bipolar I Disorder

Protocol summary

Study aim

Comparison of Adjunctive Quetiapine Versus Adjunctive Haloperidol in Combination with Sodium Valproate for Treatment of Patients with Mania or Mixed phase of Bipolar I Disorder

Design

Randomized, parallel group clinical trial with blinded outcome assessment in 40 patients with bipolar I disorder (a randomization software will be used for this purpose).

Settings and conduct

Considering the importance of the rapid elimination of the symptoms of the acute episode of mania, the present study explored the individual comparison of the therapeutic effects of Sodium Valproate combined with Quetiapine or Haloperidol among patients with bipolar I disorder experiencing an episode of mania or mixed feature admitted to Razi Psychiatric Center of Tehran. All patients and individuals who will be contributing to this trial will be blind to the data.

Participants/Inclusion and exclusion criteria

Patients aged 18 years or above Patients with mania or mixed feature bipolar I disorder according to DSM-5 criteria, diagnosed as per a psychiatric interview A history of sensitivity to sodium valproate, quetiapine, and haloperidol A history of systemic diseases Experiencing pregnancy and breastfeeding The presence of substance use disorders A history of brain blood vessels disease and head trauma HIV positive patients and uncontrolled diabetic patients

Intervention groups

Patients with mania or mixed phase of Bipolar I Disorder, who will be receiving two different treatment protocols.

Main outcome variables

The duration of the signs and symptoms of active phase
The intensity of the signs and symptoms of active phase
Treatment compliance

General information

Reason for update

Acronym

BQS

IRCT registration information

IRCT registration number: **IRCT20150221021168N3**

Registration date: **2021-05-06, 1400/02/16**

Registration timing: **prospective**

Last update: **2021-05-06, 1400/02/16**

Update count: **0**

Registration date

2021-05-06, 1400/02/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 33401604

Email address

me.samiei@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of Adjunctive Quetiapine Versus Adjunctive Haloperidol in Combination with Sodium Valproate for Treatment of Patients with Mania or Mixed Feature Bipolar I Disorder

Public title

A Comparison of Adjunctive Quetiapine Versus Adjunctive Haloperidol in Combination with Sodium Valproate for Treatment of Patients with Bipolar I Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients of 18 years or above Patients were diagnosed with Bipolar I disorder experiencing an episode of acute mania or mixed feature according to psychiatric interview All participants voluntarily provided a written informed consent form

Exclusion criteria:

History of Sensitivity to Sodium Valproate , Quetiapine and Haloperidol History of Neurological , Cardiovascular , Respiratory, Blood , kidney, Hepatic , Endocrine, Immunological and other Systemic Disease Pregnancy and Breastfeeding Period HIV Positive and Uncontrolled Diabetic patients Substance Use Disorders History of Brain Blood Vessels Diseases and Head Trauma

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software will be used for the randomization of two parallel groups in this trial .
(<https://www.randomization.com>)

Blinding (investigator's opinion)

Double blinded

Blinding description

All parties of this clinical trial will remain unaware of the treatment allocation and grouping. Patients, investigators, and healthcare providers will be independent individuals and blinded to the treatment received by the patients.

Placebo

Not 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 Sciences , Koodakyar End close , Student Blvd , Zip Code : 1985713870 , Tehran , Iran

City

Tehran

Province

Tehran

Postal code

1985713870

Approval date

2019-10-08, 1398/07/16

Ethics committee reference number

IR.USWR.REC.1398.195

Health conditions studied

1

Description of health condition studied

Bipolar Mood Disorder with Mania or Mixed feature

ICD-10 code

F31.13

ICD-10 code description

Bipolar disorder, current episode manic without psychotic features, severe Bipolar disorder , current episode mixed

Primary outcomes

1

Description

The relevant mania score obtained by the Young Mania Rating Scale

Timepoint

The assessment of treatment response prior the beginning of the study, as well as 3 and 6 weeks after the study onset

Method of measurement

Young Mania Rating Scale

Secondary outcomes

1

Description

The extent of drowsiness

Timepoint

Three and six weeks after the onset of the study

Method of measurement

The Epworth Sleepiness Scale

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

First Intervention group: Patients with bipolar 1 disorder with the most recent episode of mania or mixed feature Sodium Valproate 15 mg/kg/day and haloperidol 10 mg/day for 42 days or 6 weeks

Category

Treatment - Drugs

2**Description**

Second Intervention group: Patients with bipolar 1 disorder with the most recent episode of mania or mixed feature Sodium Valproate 15 mg/kg/day with Quetiapine 500mg/day for 42 days or 6 weeks

Category

Treatment - Drugs

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

Razi Psychiatric Hospital

Full name of responsible person

Gita Sadighi

Street address

Razi Psychiatric Hospital , Amin Abad Road , Rey City , Tehran , Iran

City

Tehran

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Phone

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

University of social welfare and rehabilitation sciences

Full name of responsible person

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Gita Sadighi

Position

Assistant Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

University of social welfare and rehabilitation sciences

Full name of responsible person

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Position

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