

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of therapeutic effect of valproate with aripiprazol versus valproate with risperidone in patients with bipolar I Disorder most recent manic or mixed episode

Protocol summary

Summary

The main objective of this study is to compare the effect of combination therapy of valproate with aripiprazole or risperidone. The effect of this combination on weight as a secondary objective will be. The study population is patients with Bipolar I Disorder. Case selection with interviews based on diagnostic criteria revised text of the Diagnostic and Statistical Manual of mental disorder (DSM IV-TR) by a psychiatrist and consider the inclusion and exclusion criteria will be enrolled in the study. The most important criterion for inclusion, will be Yang scale more than 17. The sample size based on the statistical power of 80% and 95% confidence intervals will be 40 people. Patients will be randomly assigned to two groups. Researchers and patients will not inform from drug and group types. 20 patients in a group valproate with aripiprazole and 20 in the other group will receive valproate with risperidone. n weeks 3 and 6 based on measurements of Yang's scores and weight data will be collected. During the study patients visit every week and will be monitored physically and mentally.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510222166N2**

Registration date: **2016-03-29, 1395/01/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-29, 1395/01/10

Registrant information

Name

ALI Nazeri Astane

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Science

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of valproate with aripiprazol versus valproate with risperidone in patients with bipolar I Disorder most recent manic or mixed episode

Public title

Aripiprazole effect in the treatment of mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :diagnosis of bipolar disorder in mania or mixed episode based on DSM-IV- TR ;patients with

YMRS >OR=17. Exclusion criteria : pregnant women ;breastfeeding women; debilitating physical and neurological illness; sever liver disease; severe kidney disease

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: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

kodakyar Ave., daneshjo Blvd.,Evin,Post code: : 1985713834

City

Tehran

Postal code

1965713834

Approval date

2015-02-23, 1393/12/04

Ethics committee reference number

uswr.rec.1393.196

Health conditions studied

1

Description of health condition studied

Bipolar Disorder type I

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

Primary outcomes

1

Description

mood and irritability

Timepoint

before intervention, after the 3 weeks and 6 weeks trial

Method of measurement

yung mania rating scaie (YMRS)

Secondary outcomes

1

Description

Weight

Timepoint

before intervention , after the 3 and 6 weeks trial

Method of measurement

balance

Intervention groups

1

Description

this study is drug intervention trial. cases divided randomly two groups.one group will receive valproate 15 mg/kg combind with aripiprazole 30 mg daily.

Category

Treatment - Drugs

2

Description

patients will receive randomly valprate 15 mg/kg and risperidone 6mg/kg in second group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

RAZI PSYCHIATRY HOSPITAL

Full name of responsible person

Nazeri Astaneh ALI

Street address

tehran - shahr rey-shahid rastegar blvd- razi psychiatry hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Social Welfare and Rehabilitation
Sciences

Full name of responsible person

mr.ADL AKBAR

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Tehran - evin-daneshjoo blvd - koodakiar st

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Tehran

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

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**

University of Social Welfare and Rehabilitation
Sciences

Full name of responsible person

Dieji Bahman

Position

psychiathry resident

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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