

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### A head to head comparison of aripiprazole versus olanzapine as adjuncts to lithium for treating manic or mixed episodes in bipolar I disorder

#### Protocol summary

##### Summary

This five week randomized control clinical trial includes 60 in-patients with bipolar mood disorder- type I with manic phase. The patients are randomly allocated either into lithium+olanzapine or aripiprazole+lithium groups. Young Mania Rating Scale is used to measure the clinical symptoms. Assessment will be occurred at baseline, week 1, week 3, and week 5.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201305213930N25**

Registration date: **2014-11-18, 1393/08/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-18, 1393/08/27

##### Registrant information

##### Name

Ahmad Ghanizadeh

##### Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1627 3070

##### Email address

ghanizad@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-09-12, 1392/06/21

##### Expected recruitment end date

2015-02-02, 1393/11/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A head to head comparison of aripiprazole versus olanzapine as adjuncts to lithium for treating manic or mixed episodes in bipolar I disorder

##### Public title

A head to head comparison of aripiprazole versus olanzapine as adjuncts to lithium for treating manic or mixed episodes in bipolar disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients from both gender aged 16 to 65 years old with bipolar mood disorder-type I- manic phase. Exclusion criteria: sever uncontrolled medical conditions such as hypothyroidism; positive history of allergy to one of the medications.

##### Age

From **16 years** old to **65 years** old

##### Gender

Both

##### Phase

3

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **60**

##### 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

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences

##### City

Shiraz

##### Postal code

--

#### Approval date

2013-08-11, 1392/05/20

#### Ethics committee reference number

CT-P-92-5542

## Health conditions studied

### 1

#### Description of health condition studied

Bipolar mood disorder manic or mixed phase

#### ICD-10 code

F30

#### ICD-10 code description

Manic episode

## Primary outcomes

### 1

#### Description

clinical symptoms of mania

#### Timepoint

baseline, week 1, week 3, and week 3

#### Method of measurement

Interview, Young Mania Rating Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Lithium (up to 1200mg/day)+Olanzapine (25mg/day)

#### Category

Treatment - Drugs

### 2

#### Description

Lithium (up to 1200mg/day)+Aripiprazole ( up to 25mg/day)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

##### Full name of responsible person

Ahmad Ghanizadeh

##### Street address

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

##### Full name of responsible person

Basi Hashemi

##### Street address

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

##### City

Shiraz

#### 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, Shiraz 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**

Shiraz University of Medical sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Position**

MD

**Other areas of specialty/work**

**Street address**

Hafez Hospital

**City**

Shiraz

**Postal code**

**Phone**

+98 71 3627 3070

**Fax**

**Email**

ghanizad@sina.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical sciences

**Full name of responsible person**

AHmad Ghanizadeh

**Position**

MD

**Other areas of specialty/work**

**Street address**

Hafez Hospital

**City**

Shiraz

**Postal code**

**Phone**

+98 71 3627 3070

**Fax**

**Email**

ghanizad@sina.tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

## 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*