

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### COMPARISON THE EFFICACY OF ADJUNCTIVE THERAPY RISPERIDON OR ARIPIPERAZOL TO LITHIUM IN BIPOLAR DISORDER(MANIC PHASE WITH PSYCHOTIC FEATHER)

#### Protocol summary

##### Summary

The object of this randomized, double blind clinical trial is to test the hypothesis that the addition of Aripiprazole to Lithium would be more effective in control of psychotic symptom in bipolar patient than Risperidon. 60 patients with ages more than 18 years who have no other medical or psychiatric conditions with DSM-IV-TR diagnosed psychotic bipolar in manic phase will receive Lithium combined with either Aripiprazole (N=30) or Risperidon(N=30) for 3 weeks. Efficacy will be defined as the change from baseline to endpoint in score on the Young mania Rating scale(YMRS). Side effects will be also evaluated using SAS,AIMS,BARS.YMRS,BPRS will be evaluated at baseline, 7,14 and 21 days.

#### General information

##### Acronym

ALD

##### IRCT registration information

IRCT registration number: **IRCT201409176691N2**

Registration date: **2015-01-27, 1393/11/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-27, 1393/11/07

##### Registrant information

###### Name

Fatemeh Sheikhmoonesi

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1328 5109

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences and Health Service

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2014-12-22, 1393/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

COMPARISON THE EFFICACY OF ADJUNCTIVE THERAPY RISPERIDON OR ARIPIPERAZOL TO LITHIUM IN BIPOLAR DISORDER(MANIC PHASE WITH PSYCHOTIC FEATHER)

##### Public title

effect of aripiprazole in treatment of psychotic mania

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

criteria: Age more than 18 years; Diagnosis of Bipolar disorder with psychotic symptom based on DSM-IV TR; Ongoing treatment with Lithium as a mood stabilizer with seromic level between 0.8-1.2meq/L ; patient with YMRA>20.Exclusion criteria: Mental Retardation; Pregnancy or Breast Inclusion feeding;Any chronic medical problem; substance abuse; Any other psychiatric Disorder in Axis I OR II;Allergic to Aripiprazole and other Atypical Antipsychotic drug ;History of epileptic disorder;

Delirium state.

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**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**

Mazandaran University of Medical Sciences

**Street address**

Vice Chancellor for Research and Technology,  
Building N.2, Moallem Square, Moallem Street Sari

**City**

sari

**Postal code**

4815466848

**Approval date**

2014-03-05, 1392/12/14

**Ethics committee reference number**

92-178

**Health conditions studied****1****Description of health condition studied**

mania

**ICD-10 code**

F31

**ICD-10 code description**

bipolar affective disorder

**2****Description of health condition studied**

bipolar disorder

**ICD-10 code**

F31

**ICD-10 code description**

bipolar affective disorder

**Primary outcomes****1****Description**

Severity of manic phase and psychotic symptom

**Timepoint**

Baseline and days 7-14-21 after beginig of treatment

**Method of measurement**

YMRS

**Secondary outcomes****1****Description**

Akatezia

**Timepoint**

days 2-4-7-10 after beginig of treatment then every weeks

**Method of measurement**

BARS

**2****Description**

extrapyramidal

**Timepoint**

days 2-4-7-10 after beginig of treatment then every weeks

**Method of measurement**

AIMS

**3****Description**

diskinesia

**Timepoint**

days 2-4-7-10 after beginig of treatment then every weeks

**Method of measurement**

SAS

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

Litium combined with Tabiet Aripiprazole(30 mg/day) as intervention group for 3 weeks.

**Category**

Treatment - Drugs

**2****Description**

Litium combined with Tablets Risperidon(6mg/day) as control group for 3weeks.

**Category**

Treatment - Drugs

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

Zare Psychiatry Hospital

**Full name of responsible person**

Dr Fatemeh Sheikhmoonesi

**Street address**

Psychiatric Department, Zare Psychiatry Hospital, Sari

**City**

sari

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Ahmadali Enayati

**Street address**Vice Chancellor for Research and Technology,  
Building N.2, Moallem Square, Moallem Street**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Fatemeh Sheikhmoonesi

**Position**

Assistant Prof. of Psychiatry, Psychiatrist

**Other areas of specialty/work****Street address**

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

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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*