Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

COMPARISION THE EFFICACY OF ADJUCTIVE THERAPY RISPERIDON OR ARIPIPERAZOL TO LITIUM IN BIPOLAR DISORDER(MANIC PHAZE WITH PSYCHTIC FEATHER)

Protocol summary

Summary

The object of this randomized,double blind clinical trial is to test the hypothesis that the addition of Aripiprazole to Litium would more effective in control of psychotic symptom in bipolar patient then Risperidon. 60 patient 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 Litium combined with either Aripiprazole (N=30) or Risperidon(N=30) for 3 week. 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)

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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

COMPARISION THE EFFICACY OF ADJUCTIVE THERAPY RISPERIDON OR ARIPIPERAZOL TO LITIUM IN BIPOLAR DISORDER(MANIC PHAZE WITH PSYCHTIC FEATHER)

Public title

effect of aripiperazole 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 Litium as a mood stabilazor 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
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Psychiatric Department, Zare Psychiatry Hospital, Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahmadali Enayati
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Vice Chancellor for Research and Technology, Building N.2, Moallem Square, Moallem Street
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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
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Person responsible for updating data

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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