

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of efficacy and side effects of combined Thiothixine-Lithium and Risperidone-Lithium treatment in psychotic bipolar patients

Protocol summary

Summary

Objective: The efficacy and side effects of combined thiothixine- lithium in treatment of patients with psychotic mania will be compared with risperidone - lithium. Method: A total of 84 hospitalized patients with diagnosis of psychotic mania as defined by DSM-IV- IR receive lithium (300 mg/TID, dose increase to achieve serum level of .8-1.2 meq/lit) and randomize to receive thiothixine (5 - 15 mg/day) or risperidone (2- 6 mg/day) for a 8-week. The dose will be adjusted according to intolerable side effects. The principle measure of outcome is Young Mania Rating Scale. Side effects will be checked by checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110203770N2**

Registration date: **2012-01-18, 1390/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-18, 1390/10/28

Registrant information

Name

Nooshin Parvaresh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1211 6328

Email address

n_parvaresh@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Neuroscience Research Center, Kerman University of Medical Sciences

Expected recruitment start date

2011-11-21, 1390/08/30

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of efficacy and side effects of combined Thiothixine-Lithium and Risperidone-Lithium treatment in psychotic bipolar patients

Public title

The Efficacy of Thiothixine In Bipolar Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- 18-60 year's old patients; 2- Psychotic mania according to DSM-IV-IR; 3- Score > 20 in Young Mania Rating Scale. Exclusion criteria: 1- Medical conditions as diabetes mellitus and epilepsy; 2- Evidence of mental retardation as IQ < 70; 3- Receiving any psychotropic medication, opioid and stimulants through four weeks before entering trial.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 84

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

Neuroscience Research Center, Kerman University Of
Medical Sciences

Street address

Neuroscience Research Center, Ebn-e-sina avenue,
Jahad blvd

City

Kerman

Postal code

Approval date

2011-11-21, 1390/08/30

Ethics committee reference number

cc/knrc/90-17

Health conditions studied

1

Description of health condition studied

Bipolar disorder, Manic phase, Psychotic

ICD-10 code

F31.2

ICD-10 code description

Bipolar Affective disorder, Current Episode Manic With
Psychotic Symptoms

Primary outcomes

1

Description

Symptoms severity of mania

Timepoint

Baseline, week 2, 4, 6 and 8 weeks after the drugs
started

Method of measurement

Young Mania Rating Scale

Secondary outcomes

1

Description

Anxiety severity

Timepoint

Baseline, week 2, 4, 6, 8.

Method of measurement

Hamilton Rating Scale for Anxiety

2

Description

Deression severity

Timepoint

Baseline, week 2, 4, 6, 8

Method of measurement

Hamilton Rating Scale for Deression

3

Description

Psychosis severity

Timepoint

Baseline, week 2, 4, 6, 8

Method of measurement

Positive and Negative Syndrome Scale

4

Description

Side effects

Timepoint

Week 2, 4, 6, 8

Method of measurement

Check list

5

Description

weight

Timepoint

baseline and the end of week 8

Method of measurement

weighing the patient

6

Description

fasting blood suger

Timepoint

baseline and the end of week 8

Method of measurement

lab

Intervention groups

1

Description

Intervention 1: Lithium at dose producing serum
concentration of .8 - 1.2 meq /lit + thiothixine with

starting dose of 5 mg and target dose of 15 mg/day.

Category

Treatment - Drugs

2

Description

Intervention 2: Lithium at dose producing serum level of .8 - 1.2 meq/lit + risperidone with starting dose of 2 mg and target dose of 6 mg/day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Nooshin Parvaresh

Street address

Shahid Beheshti Hospital, Jomhouri Islami blvd

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neuroscience Research Center, Kerman University Of Medical Sciences

Full name of responsible person

Dr.Vahid Sheibani

Street address

Neuroscience Research Center, Ebn-e-sina avenue, Jahad blvd

City

Kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Neuroscience Research Center, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Nooshin Parvaresh

Position

MD, assistant professor

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Jomhouri Islami blvd

City

Kerman

Postal code

Phone

+98 34 1211 6328

Fax

Email

n_parvaresh@kmu.ac.ir, n_parvaresh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Nooshin Parvaresh

Position

MD, assistant professor

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Jomhouri Islami blvd

City

Kerman

Postal code

Phone

+98 34 1211 6328

Fax

+98 34 1211 0856

Email

n_parvaresh@kmu.ac.ir, n_parvaresh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Nooshin Parvaresh

Position

MD, assistant professor

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Jumhouri Islami blvd

City

Kerman

Postal code

7618834115

Phone

+98 34 1211 6328

Fax

+98 34 1211 0856

Email

n_parvaresh@kmu.ac.ir, n_parvaresh@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty