

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A double - blind placebo controlled trial of tamoxifen added to lithium in patient with acute mania

Protocol summary

Summary

This study will assess the efficacy and safety of tamoxifen as an adjunctive agent to lithium and risperidone for the treatment of acute mania in hospitalized bipolar patients. Methods: patients aged between 18 and 49 will be eligible to participate, as they met the DSM-IV criteria for a current manic episode, on the basis of a clinical interview by two academician psychiatrists. In addition, a score of at least 20 points on the Young Mania Rating Scale will be required representing at least a moderate-to-severe mania. Exclusion: Other diagnosis in Axis 1, substance dependence, severe medical problems and lactating and pregnant women. Patients will be randomly allocated to lithium (1-1.2 mEq/L) + risperidone + tamoxifen (80 mg/day) (group A) or lithium (1-1.2 mEq/L) + risperidone + placebo (group B) for an 6-week, double-blind, placebo-controlled study. Patients were assessed by a third year resident of psychiatry at baseline and at 7, 14, 28, 42, days after the medication started. The mean decrease in the Young Mania Rating Scale score from baseline will be used as the main outcome measure of response of mania to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT1138901151556N12**

Registration date: **2010-04-29, 1389/02/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-04-29, 1389/02/09

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical sciences

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2010-05-01, 1389/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double - blind placebo controlled trial of tamoxifen added to lithium in patient with acute mania

Public title

tamoxifen added to lithium in patient with acute mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged between 18 and 49 will be eligible to participate, as they meet the DSM-IV criteria for a current manic episode, on the basis of a clinical interview by two academician psychiatrists. In addition, a score of at least 20 points on the Young Mania

Rating Scale will be required representing at least a moderate-to-severe mania. Exclusion criteria: Other diagnosis in Axis 1, substance dependence, severe medical problems and lactating and pregnant women.

Age

From **18 years** old to **49 years** old

Gender

Both

Phase

2

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2009-05-12, 1388/02/22

Ethics committee reference number

6965

Health conditions studied

1

Description of health condition studied

Mania episode

ICD-10 code

F30

ICD-10 code description

Mania episode

Primary outcomes

1

Description

Score of Young Mania Rating Scale

Timepoint

every two weeks from the beginning of trial till week 8

Method of measurement

by Young Mania Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Risperidone tablet(4 mg/day) combined with tamoxifen tablet (80 mg/day) + lithium tablet 1800mg/day as intervention group for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Risperidone tablet (4 mg/day) combined with placebo tablet + lithium tablet 1800mg/day as control group for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Prof. Shahin Akhondzadeh

Street address

Roozbeh Hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Department of Psychiatry

Full name of responsible person

Dr. Bahman Salehi

Street address

Arak University of Medical Sciences

City

Arak

3

Recruitment center

Name of recruitment center

Department of Psychiatry
Full name of responsible person
Dr. Farzin Rezaei
Street address
Kordistan University of Medical Sciences
City
Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Keshavarz Blvd
City
Tehran

Grant name

6965

Grant code / Reference number

6965

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

Yes

Title of funding source

Tehran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical sciences
Full name of responsible person

Prof. Shahin Akhondzadeh
Position
Ph.D.
Other areas of specialty/work
Street address
Roostbeh Hospital
City
Tehran
Postal code
Phone
+92 1554 12222
Fax
Email
s.akhond@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Shahin Akhondzadeh
Position
ph.D.
Other areas of specialty/work
Street address
Roostbeh Hospital
City
Tehran
Postal code
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+98 21 5541 2222
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Email
s.akhond@sina.tums.ac.ir
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