

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Investigation of efficacy of lithium and tamoxifen in the treatment of acute mania in bipolar affective disorder.

Protocol summary

Summary

There are not appropriate responses for monotherapy in prepubertal or early onset bipolar disorder and a few controlled trials exist for combined therapy in them. Some studies have been conducted about the role of tamoxifen in the treatment of bipolar disorder in adults. This study is designed to investigate the efficacy AND tolerability of combined tamoxifen and lithium treatment in youths (10-20 years old) with acute mania in hospitalized bipolar patients. This is a randomized placebo-controlled clinical trial in 2013-2014 in a 3-week. 44 adolescents with diagnosis of bipolar disorder is randomized for treatment with lithium plus tamoxifen (n=22) or lithium plus placebo (n=22). In addition, a score of at least 20 points of the young mania rating scale are required and known sensitivity to tamoxifen or lithium is the exclusion criteria. The primary outcome measure is young mania rating scale and child depression inventory scale. The serum level of lithium and side effects evaluate weekly, and reduction in Young Mania score of less than 50% of the initial value is considered as a therapeutic response.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410126418N3**
Registration date: **2015-02-27, 1393/12/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-27, 1393/12/08

Registrant information

Name

Soroosh Arman

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 313 2535

Email address

arman@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of efficacy of lithium and tamoxifen in the treatment of acute mania in bipolar affective disorder.

Public title

Tamoxifen Effects in Acute mania in Youth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria Consistent 9-22 years old with current manic episode (with or without psychotic feature) as diagnosed by means of the structured clinical interview for Axis I DSM-IV disorders-Patient version (SCDI-P). A score of at least 20 points on the Young Mania Rating Scale was required representing at least a moderate-to-severe mania. Exclusion Criteria: Neurological or other

medical impairment- The need for ongoing treatment with other psychoactive medications and/or current substance dependence- Mental Retardation (IQ<70)- History of renal or liver function impairments- History of coagulopathy,

Age

From **9 years** old to **22 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Medicin college of Isfahan University of Medical Sciences

Street address

Hezar Jarib St.-Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2014-09-17, 1393/06/26

Ethics committee reference number

393501

Health conditions studied

1

Description of health condition studied

mania in youth

ICD-10 code

F31.1-F31.

ICD-10 code description

A disorder characterized by two or more episodes in which the patient's mood and activity levels are significantly disturbed, this disturbance consisting on

some occasions of an elevation of mood and increased energy and activity (hypomania or mania) and

Primary outcomes

1

Description

Young Mania Rating Scale

Timepoint

First Week-Second Week-Third Week

Method of measurement

Questionair

Secondary outcomes

1

Description

Child Depression Rating Scale

Timepoint

First Week-Second Week- Third Week

Method of measurement

Questionair

Intervention groups

1

Description

intervention goup are randomly allocates in to lithium (1-1/2meq/lit)+tamoxifen(40mg/day)(Group A)for a3weeks.The principle measures of outcomeare the Young Mania Rating Scale and Child Depresion Inventory scale,and measure evaluate weekly.

Category

Treatment - Drugs

2

Description

Control goup are randomly allocates into lithium (1-1/2meq/lit)+placebo(Group B)for a3weeks.The principle measures of outcomeare the Young Mania Rating Scale and Child Depression Inventory scale,and measure evaluate weekly.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Child Psychiatric ward- Alzahra Hospital

Full name of responsible person

Alzahra Hospital-Psychiatric Resident-Elham Fallah

Street address

Shohadaye Soffeh St.

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Soroor Arman

Street address
Isfahan University of Medical Sciences-Psychiatry
group

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Isfahan 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
Isfahan University of Medical Sciences

Full name of responsible person
Elham Fallah

Position
Psychiatric Resident

Other areas of specialty/work

Street address
Shahid Mahdavi St., Bahar Av., HezarJarib St. , Isfahan
City

City
Isfahan

Postal code

Phone
+98 31 3668 1836

Fax

Email
elhamfallah51@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Dr.Soroor Arman

Position
Master

Other areas of specialty/work

Street address
Sheikh Koleini St., HezarJarib St., Isfahan City

City
Isfahan

Postal code

Phone
+98 312222135

Fax
+98 312222135

Email
arman@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Elham Fallah

Position
Psychiatric Resident

Other areas of specialty/work

Street address
Shahid Mahdavi St., Bahar Av., HezarJarib St. , Isfahan
City

City
Isfahan

Postal code

Phone
+98 31 3668 1836

Fax

Email
elhamfallah51@yahoo.com

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