

# 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

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##### 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

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**Position**  
Psychiatric Resident

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#### Person responsible for scientific inquiries

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Master

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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*