

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Evaluation of Aspirin efficacy in prevention of erectile dysfunction due to lithium administration in comparison with placebo

#### Protocol summary

##### Summary

The goal of this study is to assess the efficacy of Aspirin in the treatment of sexual dysfunction induced by lithium. Forty patients, who are in remission phase of bipolar disorder and are on lithium maintenance and have sexual dysfunction based on international index of erectile function, will be entered into our study. Patients will be excluded if they have other psychiatric comorbidity, substance dependence, GI bleeding. Before entering into the study, informed consent will be obtained. The serum level of lithium should be 0.6-1.00 MEq/lit. One group will receive Aspirin (coated) 240 mg/day and the second group will receive Placebo for 6 weeks. During the trial, patients will be assessed by international index of erectile function.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138711131556N4**

Registration date: **2009-02-12, 1387/11/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2009-02-12, 1387/11/24

##### 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

2009-02-20, 1387/12/02

###### Expected recruitment end date

2010-02-20, 1388/12/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluation of Aspirin efficacy in prevention of erectile dysfunction due to lithium administration in comparison with placebo

###### Public title

Aspirin in the treatment of sexual dysfunction

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion Criteria: Remission phase of bipolar disorder, maintenance on lithium, sexual dysfunction based on international index of erectile function. Exclusion Criteria: Other psychiatric comorbidity, substance dependence, GI bleeding.

###### Age

From **20 years** old to **45 years** old

###### Gender

Male

###### 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

Tehran University of Medical Sciences, Keshavarz Blv

##### City

Tehran

##### Postal code

#### Approval date

2009-01-22, 1387/11/03

#### Ethics committee reference number

8146

## Health conditions studied

### 1

#### Description of health condition studied

Sexual dysfunction

#### ICD-10 code

F52

#### ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

## Primary outcomes

### 1

#### Description

Score of international index of erectile function

#### Timepoint

every two week

#### Method of measurement

use of international index of erectile function

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Asprin (80 mg TDS) as intervention group

#### Category

Treatment - Drugs

### 2

#### Description

Tab Placebo as control group

#### Category

empty

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Roozbeh psychiatric Hospital

##### Full name of responsible person

Dr. Seyed Ali Ahmadi Abhari

##### Street address

Roozbeh psychiatric Hospital, South Kargar

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. akbar Fotouhi

##### Street address

Tehran University of Medical Sciences, Keshavarz Blvd

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### 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., FBPharmacolS., Prof. of Clinical  
Psychopharmacology

**Other areas of specialty/work**

**Street address**

Roozbeh Psychiatric Hospital

**City**

Tehran

**Postal code**

13337

**Phone**

+98 21 5541 2222

**Fax**

+98 21 5541 9113

**Email**

s.akhond@sina.tums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Ph.D., FBPharmacolS., Prof. of Clinical  
Psychopharmacology

**Other areas of specialty/work**

**Street address**

Roozbeh Psychiatric Hospital

**City**

Tehran

**Postal code**

13337

**Phone**

+98 21 5541 2222

**Fax**

+98 21 5541 9113

**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*