

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Effect of Minocycline as adjuvant therapy for the acute phase of mania: A randomized, double-blind, placebo-controlled trial

#### Protocol summary

##### Study aim

Investigating the effect of Minocycline for the treatment of the acute phase of mania

##### Design

Randomized double blind and placebo-controlled clinical trial.

##### Settings and conduct

This study will be performed on patients attending Roozbeh Hospital. Patients who meet the inclusion and exclusion criteria will be included.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of bipolar disorder based on DSM-V criteria - Age between 55-18 years - The score of 20 (at least) based on Young Mania Rating Scale.

Exclusion criteria: Systemic disease including hypothyroidism or hyperthyroidism - Cardiac conduction disorder - Drug dependence except nicotine and caffeine - Presence of serious suicide risk - IQ less than 70 -

History of allergy to any of the used drugs - Pregnant and lactating women - The use of drugs that cause symptoms similar to mania like psychostimulants

##### Intervention groups

Control group: patients receive 900 mg of lithium, 4 mg of risperidone, and placebo, daily. Intervention group: patients receive 900 mg of lithium, 4 mg of risperidone, and 100 mg of minocycline, daily.

##### Main outcome variables

Mania severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090117001556N155**

Registration date: **2023-12-03, 1402/09/12**

Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**

Update count: **0**

##### Registration date

2023-12-03, 1402/09/12

##### 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

##### Expected recruitment start date

2024-01-21, 1402/11/01

##### Expected recruitment end date

2026-01-21, 1404/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Minocycline as adjuvant therapy for the acute phase of mania: A randomized, double-blind, placebo-controlled trial

##### Public title

Minocycline for the treatment of the acute phase of mania

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Diagnosis of bipolar disorder based on DSM-V criteria  
Age between 55-18 years The score of 20 (at least) based on Young Mania Rating Scale

**Exclusion criteria:**  
Systemic disease including hypothyroidism or hyperthyroidism Cardiac conduction disorder Drug dependence except nicotine and caffeine Presence of serious suicide risk IQ less than 70 History of allergy to any of the used drugs Pregnant and lactating women The use of drugs that cause symptoms similar to mania like psychostimulants

**Age**  
From **18 years** old to **55 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**

Ethics Committee of School of Medicine, Tehran  
University of Medical Sciences

### **Street address**

Tehran University of Medical Sciences, Pour Sina St.,  
Qods St., Enghelab St.

### **City**

Tehran

### **Province**

Tehran

### **Postal code**

1417653761

### **Approval date**

2023-11-01, 1402/08/10

### **Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1402.429

## Health conditions studied

### 1

#### **Description of health condition studied**

Bipolar disorder

#### **ICD-10 code**

F31

#### **ICD-10 code description**

Bipolar disorder

## Primary outcomes

### 1

#### **Description**

The severity of manic phase symptoms

#### **Timepoint**

Weeks: 0 - 2 - 4 - 6

#### **Method of measurement**

By Young Mania Rating Scale (YMRS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### **Description**

Control group: patients receive 900 mg of lithium, 4 mg of Risperidone, and placebo, daily for 6 weeks.

#### **Category**

Placebo

### 2

#### **Description**

Intervention group: patients receive 900 mg of lithium, 4 mg of Risperidone, and 100 mg of Minocycline, daily for 6 weeks.

#### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Roozbeh Hospital

**Full name of responsible person**

Dr. Mohammad Reza Mohammadi

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

mohammadimr@tums.ac.ir

## 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

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 5541 2222

**Email**

afotouhi@tums.ac.ir

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhondzadeh

**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

s.akhond@sina.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhondzadeh

**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

s.akhond@sina.tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhondzadeh

**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

s.akhond@sina.tums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The data will be distributed through final report

**When the data will become available and for how long**

5 years from 2023 to 2028

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Users should cite the resource of data

**From where data/document is obtainable**

Prof. Shahin Akhondzadeh

**What processes are involved for a request to access data/document**

By e-mail

**Comments**