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
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City
Tehran
Province
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s.akhond@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
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Dr. Shahin Akhondzadeh
Position
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Tehran
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Tehran
Postal code
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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