Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on the effect of loading dose of lithium carbonate+ Quetiapine and standard dose of lithium carbonate+ Quetiapine on acute mania

Protocol summary

Study aim
A comparative study on the effect of loading dose of lithium carbonate+ quetiapine and standard dose of lithium carbonate+ quetiapine on acute mania

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 60 patients. For randomization, random allocation was done in the form of a random permutation block of 4, and sampling is done based on a random list.

Settings and conduct
Patients are randomly selected from the hospitalized patients in the Ibn Sina emergency department (diagnosed with bipolar type one phase of mania). Possible complications in the intervention group are monitored.

Participants/Inclusion and exclusion criteria
known cases of Bipolar type 1 disorder (B1D) in acute manic phase, admitted in emergency department of ibn sina hospital

Intervention groups
Lithium loading dose+quetiapine group- Lithium routine dose+quetiapine

Main outcome variables
changes in ymrs score, ECG, renal and thyroid functuon test, serum lithium level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181204041847N2**
Registration date: **2023-08-16, 1402/05/25**
Registration timing: **retrospective**

Last update: **2023-08-16, 1402/05/25**
Update count: **0**

Registration date
2023-08-16, 1402/05/25

Registrant information

Name
Ebrahim Moghimi-Sarani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3647 9319

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-15, 1402/02/25

Expected recruitment end date
2023-07-01, 1402/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study on the effect of loading dose of lithium carbonate+ Quetiapine and standard dose of lithium carbonate+ Quetiapine on acute mania

Public title
A comparative study on the effect of loading dose of lithium carbonate+ Quetiapine and standard dose of lithium carbonate+ Quetiapine on acute mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

known cases of Bipolar type 1 disorder (B1D) Acute manic phase No consumption of lithium carbonate since at least ten days ago.

Exclusion criteria:

patients with each kind of cardiac conditions or any positive past history of cardiac diseases- any abnormal findings in their first ecg during this admission(arrhythmia, ST change,...) positive history of psoriasis hypothyroidism or hyperthyroidism cases of chronic kidney disease or acute kidney injury any allergy or history of anaphylaxis with lithium carbonate

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method in this study will be the permutation block randomization method, such that "A" represents the subject receiving the intervention, and "B" represents the subject who receives the placebo. This method is based on 15 blocks in 4 permutations, taking into account all possible quadruple permutations (AABB, ABAB, ABBA, BAAB, BBAA and BABA) and assigning zero to nine (according to a random number table) to each of these permutations, Runs. (AABB Code 0, BABA Code 1, AABB Code 2, BBAA Code 3, BAAB Code 4, and ABBA Code 5 to 9) Then, using a random number table, 15 randomly selected (rows or columns) are selected, and the assigned permutation is written to each number. (The order of placing permutations next to each other is left to right respectively) and how all 60 people will be assigned to two groups A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

participants are divided to two groups(treatment and control) and no one is aware of the treatment they are given but their clinical caregivers. to keep the cases blinded, during obtaining informed consent, it is explained to the patient that by entering this study, they may be placed in any of the control or treatment groups. After obtaining informed consent, the researcher conducts interviews and related follow-ups and does not know which group each patient belongs to. The caregiver, who is the head nurse of the ward in this research, records the patients' information about which group each patient belongs to and keeps it with them until the time of data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Karim Khan Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-02-07, 1401/11/18

Ethics committee reference number

IR.SUMS.MED.REC.1401.530

Health conditions studied

1

Description of health condition studied

Bipolar 1 disorder (acute manic phase)

ICD-10 code

F31.2

ICD-10 code description

Bipolar disorder, current episode manic severe with psychotic features

Primary outcomes

1

Description

grades on basis of Young mania rating scale (YMRS)

Timepoint

days: 0- 3-7-14

Method of measurement

(YMRS)Young mania rating scale

Secondary outcomes

1

Description

ecg change

Timepoint
pre medication (day 0), day 3, day 7, day 14
Method of measurement
any ecg change in comparison with baseline

2

Description
renal function
Timepoint
day 0,5,10
Method of measurement
serum bun, cr

3

Description
serum lithium level
Timepoint
day 0,7,14
Method of measurement
serum lithium lab test

Intervention groups

1

Description
Intervention group: receive loading dose of lithium carbonate (20 mg/kg) in form of a stat dose.
Category
Treatment - Drugs

2

Description
Control group: this group receives routine dose of Lithium carbonate (300 mg TiD)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn-e-sina Hospital
Full name of responsible person
Ebrahim Moghimi Sarani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Ebrahim Moghimi Sarani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Patients' data will be published as ymrs scores. only the patr including major data

When the data will become available and for how long

6 months after publication

To whom data/document is available

only for ethics comitee

Under which criteria data/document could be used

for further researches

From where data/document is obtainable

psychiatry department, Shiraz university of medical sciences

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

written letter of the ethics comittee

Comments