

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Quetiapine versus placebo in the treatment of obsession symptoms in bipolar patients with lithium + benzodiazepin medication, A double blind randomized controlled clinical trial

Protocol summary

Study aim

comparison of Quetiapine versus placebo in the treatment of obsession symptoms in bipolar patients with lithium + benzodiazepin medication

Design

Randomised, double blinded controlled, parallel group clinical trial

Settings and conduct

40 patients with bipolar disorder and obsessional symptom were divided randomly in basis of block permutation into two groups of intervention and control. 20 patients in intervention group give quetiapine with lithium and benzodiazepin. 20 other patient in control group give placebo instead of quetiapine. The patients and supervisor physician do not know about kind of groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients with impression of bipolar disorder according to DSM-V. The patients have score of more than 16 in Yale Brown score. The patients have score of equal or lesser than 17 in Young mania questionnaire. The patients have score of equal or lesser than 7 in Hamilton depression questionnaire. Exclusion criteria: The patients in acute phase of depression or mania. The patients with cardiac, respiratory, renal or GI disorder. Pregnant patients.

Intervention groups

The patients divided into two groups. The first group give quetiapine for 12 weeks with lithium and benzodiazepin and control group give placebo instead of quetiapine.

Main outcome variables

Evaluate severity of obsession after treatment with quetiapine in bipolar patient.

General information

Reason for update

According to assessment of previous paper we change time of prescribe medication to 8 weeks.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190307042963N1**

Registration date: **2019-04-14, 1398/01/25**

Registration timing: **prospective**

Last update: **2019-12-08, 1398/09/17**

Update count: **1**

Registration date

2019-04-14, 1398/01/25

Registrant information

Name

Bahareh Ghahramanpouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3649 0551

Email address

bahareh.ghahramanpouri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Quetiapine versus placebo in the treatment of obsession symptoms in bipolar patients with lithium + benzodiazepin medication, A double blind randomized controlled clinical trial

Public title

Analysis of treatment with quetiapin in bipolar patients with obsessional symptom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients with impression of bipolar disorder according to DSM-V. The patients have score of more than 16 in Yale Brown score. The patients have score of equal or lesser than 17 in Young mania questionnaire. The patients have score of equal or lesser than 7 in Hamilton depression questionnaire.

Exclusion criteria:

The patients in acute phase of depression or mania. The patients with cardiac, respiratory, renal or GI disorder. Pregnant patients.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

They were divided randomly in basis of block permutation into two groups of intervention and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients divided into two groups according to table of random number. One group give quetiapin and another one give placebo. The patients and supervisor physician do not know about kinds of group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University Medical Sciences

Street address

Zand Street, Medical Science University

City

Shiraz

Province

Fars

Postal code

7194685115

Approval date

2019-04-07, 1398/01/18

Ethics committee reference number

IR.SUMS.MED.REC.1398.008

Health conditions studied

1

Description of health condition studied

Bipolar disorders

ICD-10 code

F06.34

ICD-10 code description

Mood disorder due to known physiological condition with mixed features

2

Description of health condition studied

Obsessive compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Evaluate severity of obsession in bipolar patients

Timepoint

Before intervention and 4, 8 and 8 weeks after intervention

Method of measurement

Yale Brown scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients give quetiapin with lithium and benzodiazepin, start with 25 mg twice daily and

increase 50 mg weekly until 200 mg daily

Category

Treatment - Drugs

2

Description

Control group: 20 patient give pelacebo with lithium and benzodiazepin

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Dr Bahareh Ghahramanpouri

Street address

Chamran Blvd, Hafez Hospital

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Bahareh.ghaheamanpouri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mohammad Javad Ashraf

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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

Bahareh Ghahramanpouri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Yale brown scal, young mania questionnaire and hamilton questionnaire of patients- Analysis of data in spss

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

this only available for people working in academic institutions

Under which criteria data/document could be used

We can give data to academic institutions by email and they can use our data with mention reference

From where data/document is obtainable

By email:bahareh.ghahramanpouri@gmail.com

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

About 1 month after receive message we send data

Comments