

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of adding Pentoxifylline to common treatments in depression in bipolar patients

Protocol summary

Study aim

The effect of adding pentoxifylline to common treatments for bipolar depression

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 86 patients. Random double block is used for randomization

Settings and conduct

Double-blind randomized controlled clinical trial, patients with type 1 and type 2 bipolar disorder who are in a depressive phase are selected. The BDRS questionnaire is completed for them. Patients are then divided into intervention and control groups, and in the control group of patients, the same common treatments for bipolar depression with placebo. (The researcher and the patient are both blind). The therapeutic effect is evaluated through the validity and reliability of the BDRS questionnaire after 4 and 8 weeks of treatment. In this way, the scores of each person (which is scored from 0 to 60) are compared before entering the study, after 4 weeks and at the end of week 8.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with bipolar disorder types one and two Criteria for not entering: Existence of another psychiatric disorder, and medical illnesses and use of anticoagulants and NSAIDs

Intervention groups

Patients with type 1 and type 2 bipolar diagnosis who are in the depressive phase are selected and completed with the BDRS (Bipolar Depression Rating Scale) questionnaire. In addition to routine treatments, they receive 400 mg of pentoxifylline or placebo daily.

Main outcome variables

BDRS questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201119049445N3**

Registration date: **2022-06-17, 1401/03/27**

Registration timing: **prospective**

Last update: **2022-06-17, 1401/03/27**

Update count: **0**

Registration date

2022-06-17, 1401/03/27

Registrant information

Name

Hajar Salimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2127

Email address

salimi85ha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding Pentoxifylline to common treatments in depression in bipolar patients

Public title

The effect of adding Pentoxifylline to common treatments in depression in bipolar patients referred to Khorshid Hospital in 1401

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 1 and 2 bipolar disorder with an age range of 18 to 60 years in the depressive phase
Diagnosis of type 1 and 2 bipolar disorder based on DSM-V criteria by a psychiatrist Have at least five classes of education

Exclusion criteria:

Existence of psychotic symptoms Existence of another psychiatric disorder Existence of hypothyroidism History of cardiovascular disease Pregnancy or breastfeeding Existence of hepatic failure Peptic ulcer Take antiplatelet drugs or anticoagulants Receiving non-steroidal anti-inflammatory drugs

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Allocation method is used, for this purpose, the researcher first determines a total sample size and then randomly assigns a set of them to group A and the rest to group B, for example 100 Balls in group A and 100 balls in group B, then the balls are randomly removed from the container without replacement and the created sequence is recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

In collaboration with the Faculty of Pharmacy of Isfahan University of Medical Sciences, drugs and placebo with the same shape, color, taste and size are produced, and a specific code is assigned to each so that both the researcher and the participants are unaware. The data are decrypted

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

No 9 ,Jordan building, 14th Ave, North Farabi St, Mardavij St

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Province

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Postal code

8168774661

Approval date

2022-04-28, 1401/02/08

Ethics committee reference number

IR.MUI.MED.REC.1401.037

Health conditions studied

1

Description of health condition studied

Depressive phase of bipolar patients type one and two

ICD-10 code

F31.3

ICD-10 code description

Bipolar disorder, current episode depressed, mild or moderate severity

Primary outcomes

1

Description

Depression score in Bipolar Depression Rating Scale questionnaire

Timepoint

At the beginning of the study, weeks 4 and 8 of the study

Method of measurement

Bipolar Depression Rating Scale questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

Before the study, weeks 4 and 8 after the study

Method of measurement

20-item BDRS questionnaire

Intervention groups

1

Description

Intervention group: Pentoxifylline tablets, 400 mg, one daily, in the morning, for two months, a product of Amin Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Control group: In addition to the usual treatments for placebo bipolar depression, one daily, in the morning, for two months, made by Isfahan School of Pharmacy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Khorshid hospital

Full name of responsible person

Hajar Salimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mortazavi

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Vice Chancellor for Research and Technology,
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hajar Salimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

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Latest degree

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Other areas of specialty/work

Psychiatrics

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable