Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of buprenorphine on the treatment of psychosis in bipolar patients with psychotic symptoms

Protocol summary

Study aim

Evaluation of the effect of buprenorphine on the treatment of psychosis in opioid-dependent bipolar patients with psychotic signs

Design

A randomized, double-blind, placebo-controlled clinical trial will be performed on 60 patients with type I BMD who will be randomly divided into two groups of 30 each.

Settings and conduct

The study will be conducted in Shahid Beheshti Hospital in Kerman. The subjects will be randomly divided into two intervention and control groups. The intervention group will receive sublingual bupronorphine and in control group placebo will be received and psychosis signs in first and fourth days are assessed by interview

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65, diagnosis of type 1 BMD (Depression episode, psychotic panel mania) (based on DSM-V criteria), primary positive symptom severity: BPRS psychotic subscale with score greater than or equal to 12, and at least two items BPRS psychotic score of 4 or higher and exclusion criteria include: 3-month history of methamphetamine use, alcohol dependence or benzodiazepines or hallucinogenic substances, methamphetamine-induced sustained psychosis diagnosis , Taking antipsychotics or mood-regulating drugs within two weeks before admission

Intervention groups

. Intervention group, sublingual buprenorphine 1-3mg daily as needed, clonazepam 1mg or 2mg daily, three gabapentin 300mg daily, clonidine 0.2mg twice or thrice daily if tolerated. The control group will receive the above medications other than the sublingual buprenorphine and will be given placebo (manufactured by the buprenorphine tablet manufacturer. They are similar in size, color, and carved on the tablet). .

Main outcome variables

The effect of sublingual bupronorphine in combination with other drugs on psychosis in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190905044703N1**
Registration date: **2019-10-05, 1398/07/13**
Registration timing: **prospective**

Last update: **2019-10-05, 1398/07/13**
Update count: **0**

Registration date

2019-10-05, 1398/07/13

Registrant information

Name

Ali Bemani Golnaabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 1006

Email address

alibemani1355@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2020-01-10, 1398/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of buprenorphine on the treatment of psychosis in bipolar patients with psychotic symptoms

Public title
Effect of buprenorphine on the treatment of psychosis in bipolar patients with psychotic symptoms

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 65 Diagnosis of type 1 BMD (Depression episode, Mania with Psychotic Leader) (based on DSM-V criteria) Initial Severity of Positive Symptoms: BPRS psychotic score with a score of 12 or greater and at least two BPRS psychotic items with a score of 4 or more

Exclusion criteria:
A history of methamphetamine use within the last 3 months Alcohol dependence or benzodiazepines or hallucinogenic substances Diagnosis of methamphetamine-induced sustained psychosis

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study 60 patients will be randomly divided into two treatment groups. The way to select groups is that they will be assigned to groups based on block randomization. Block size 4 is considered. So we will have six blocks containing BBAA, ABAB, BABA, AABB, ABBA, BAAB. Each block will also be randomly selected using a dice throw. For example, if dice 4 is thrown, the AABB block is considered, so the first two patients are assigned to treatment A and the next two patients to treatment B. The dice will be thrown 15 times to complete the patient assignment to the treatment groups. The treatment will also be assigned to the treatment and control groups based on the accident (coin toss)

Blinding (investigator's opinion)
Double blinded

Blinding description
We randomly divided the treatment groups (sublingual buprenorphine) and the control group (placebo tablets) so that patients in these groups were unaware of the treatment assignment and the treating physician of these patients was unaware of the treatment assignment in the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
Kerman University of Medical Sciences, Vice Chancellor for Research and Technology, Ibn Sina Ave.

City
Kerman

Province
East Azarbaijan

Postal code
7616913911

Approval date
2018-06-27, 1397/04/06

Ethics committee reference number
IR.KMU.REC.1397.463

Health conditions studied

1

Description of health condition studied
Psychosis

ICD-10 code
F15

ICD-10 code description
Other stimulant related disorders

Primary outcomes

1

Description
Psychosis leaderboard

Timepoint
The first day before the intervention and the fourth day after the intervention

Method of measurement
interview

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Intervention

group, sublingual buprenorphine 1 to 2 mg as needed, clonazepam 1 or 2 mg as needed, three gabapentin 300 mg daily, clonidine 0.2 half daily twice or thrice if needed. Tolerate the side effects

Category

Treatment - Drugs

2

Description

Control group: Control group: Control group will receive the above drugs except sublingual buprenorphine and will be given placebo (made by buprenorphine tablet manufacturer. To be.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Shahid Beheshti Hospital

Full name of responsible person

Ali Bemani Golnaabadi

Street address

Kerman, Republic Boulevard, Agriculture Boulevard, Shahid Beheshti Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Payakhti

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Ibn Sina St.

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Ali Bamani Glena Abadi

Position

Resident of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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