Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Comparison of the efficacy and safety of adjunctive therapy using Ketamine with Bupronorphine for patients with major depressive disorder and contaminant opium abuse: A randomized double blind, placebo-controlled clinical trial

Protocol summary

Study aim
Comparison the efficacy and safety of adjunctive therapy using ketamine with buprenorphine for of patients with major depressive disorder and concomitant opium abuse.

Design
Double-blind, randomized , placebo-controlled clinical trial with with parallel groups, , phase 2 on 60 patients. Randomization will be performed using Number cruncher software.

Settings and conduct
This study is performed on patients admitted to Ebn Sina Psychiatric Hospital in Shiraz with a diagnosis of major depressive disorder and concomitant opioid use disorder. Patients are randomly divided into two groups of 30, one receiving ketamine and one receiving buprenorphine. Depression, anxiety and suicidal ideation of patients before and after medication are measured by Beck Depression Inventory, Beck Suicide Inventory and Hamilton Anxiety Inventory.

Participants/Inclusion and exclusion criteria
Patients admitted in the Ebne Sina hospital wards between the ages of ۱۸ and ۶۵ who meet the diagnostic criteria for major depressive disorder and at the same time suffer from opium use disorder. They should not suffer from important psychiatry problems or internal diseases such as heart disorders, lung diseases, rheumatic diseases, Epilepsy, cancer and thyroid disease at same time.

Intervention groups
Intervention group A: Patients with major depression and concomitant use of opioids receiving ketamine injection and placebo oral drug Intervention group B: Patients with major depression and concomitant use of opioids receiving placebo injection and oral buprenorphine

Main outcome variables
Depression severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211214053411N1**
Registration date: **2022-02-10, 1400/11/21**
Registration timing: **prospective**

Last update: **2022-02-10, 1400/11/21**
Update count: **0**

Registration date
2022-02-10, 1400/11/21

Registrant information

Name
Arash Mansoori

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3823 3148

Email address
arashmansoori59@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the efficacy and safety of adjunctive therapy using Ketamine with Bupronorphine for patients with major depressive disorder and contaminant opium abuse: A randomized double blind, placebo- controlled clinical trial

Public title
Comparison of the effectiveness of ketamine with buprenorphine in depression associated with opium use

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients admitted to Ebn Sina Hospital in Shiraz with a diagnosis of major depression or depression induced by opioid use Age between 18 and 60 years Opium user according to DSM5 criteria

Exclusion criteria:
Having a major comorbid psychiatric illness such as psychosis or bipolar spectrum Having major physical illnesses such as cardiovascular disease - Uncontrolled blood pressure - Uncontrolled diabetes - Uncontrolled thyroid disease

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random list is created by a statistician using the Number Cruncher statistical system (NCSS statistical software system) using the simple block random method. Then, the eligible patients will be divided into two categories according to a random list by our fellow researcher in charge of the ECT unit of Ebne Sina Hospital (where ketamine treatment is performed by anesthesiologist). All participants and researchers are blind to patient allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, the main researcher, and those who evaluate the outcome to analyze the data and those who prepare the draft article, are kept blinded by blind studies. Only those who have not blinded in this study are nurses responsible for injection of intravenous drugs, which are not involved in the process of evaluating patients before and after intervention. Considering that in both groups, the patients will receive injectable and oral drugs, for blinding the researcher and patient , two types of similar packages with opaque coating will be prepared, which first type contains of normal saline bottle, distilled water vial and bopronurfin pills and the other type package contains normal saline bottle, ketamine vial and placebo pills. Packages are numbered based on the random list. After completing the study, the list of packages will be decoded by the researcher. The nurses that inject the drug will also be reminded that they will not provide information on the content of the packages to researcher or patients. The shape of vials and serum and tablets will be very similar.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz Medical School

Street address
Unit 1, Negin building, Alley no. 17, Shahid fallahi st., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7185654787

Approval date
2021-09-21, 1400/06/30

Ethics committee reference number
IR.SUMS.MED.REC.1400.333

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F32

ICD-10 code description
Major depressive disorder, single episode

2

Description of health condition studied
Suicide idea

ICD-10 code
R45.8

ICD-10 code description

Other symptoms and signs involving emotional state

3

Description of health condition studied
Opioids abuse
ICD-10 code
F11
ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Depression
Timepoint
Before the intervention, the day of the intervention, 24 hours after the intervention, one week after the intervention
Method of measurement
Beck Depression Inventory

Secondary outcomes

1

Description
Anxiety
Timepoint
Before the intervention, the day of the intervention, 24 hours after the intervention, one week after the intervention
Method of measurement
Hamilton Anxiety Questionnaire

2

Description
Suicide idea
Timepoint
Before the intervention, the day of the intervention, 24 hours after the intervention, one week after the intervention
Method of measurement
Beck suicide questionnaire

Intervention groups

1

Description
Intervention-control group A: Patients in this group receive infusion ketamine as an intervention and oral placebo tablet as control. . Ketamine hydrochloride will receive at a dose of 0.5mg/kg, diluted in 0.9% saline, over a 40-minute period by intravenous pump. In addition, two placebo pills will take sublingually
Category
Treatment - Drugs

2

Description
Intervention-control group B: Patients will receive oral buprenorphine as intervention and saline infusion as placebo.In this group, patients take two buprenorphine 8 mg tablets sublingually. In addition, they will receive 0.9% normal saline serum for 40 minutes by intravenous pump
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebne sina hospital
Full name of responsible person
Dr. Amir Bazrafshan
Street address
Ebne sina hospital, Hafez St., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3228 9601
Fax
+98 71 3228 0236
Email
sinahosp@sums.ac.ir
Web page address
http://ebnesina.sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Amir Bazrafshan
Street address
Opposite Palestine Street, Zand St., Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
Web page address
http://sums.ac.ir
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
Dr. Amir Bazrafshan

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Psychiatry department, Hafez hospital, Chamran Blvd., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7194634786

Phone
009871336479531

Email
bazrafshan_amir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Amir Bazrafshan

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychology

Street address
Psychiatry department, Hafez hospital, Chamran Blvd., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7194634786

Phone
+98 71 3647 9531

Email
bazrafshan_amir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Arash Mansoori

Position
Psychiatry resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Unit 1, Negin building, Alley no. 17, Shahid Fallahi St., Shiraz, Irant.,

City
Shiraz

Province
Fars

Postal code
7185654787

Phone
+98 71 3823 3148

Email
arashmansoori59@gmail.com

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