

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the efficacy and safety of adjunctive therapy using Ketamine with Buprenorphine 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 18 and 60 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)

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+98 71 3823 3148

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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		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.	
Scientific title		Placebo	
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		Used	
Public title		Assignment	
Comparison of the effectiveness of ketamine with buprenorphine in depression associated with opium use		Parallel	
Purpose		Other design features	
Treatment			
Inclusion/Exclusion criteria		Secondary Ids	
Inclusion criteria:		empty	
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		Ethics committees	
Exclusion criteria:		<u>1</u>	
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		Ethics committee	
Age		Name of ethics committee	
From 18 years old to 60 years old		Ethics Committee of Shiraz Medical School	
Gender		Street address	
Both		Unit 1, Negin building, Alley no. 17, Shahid fallahi st., Shiraz, Iran	
Phase		City	
N/A		Shiraz	
Groups that have been masked		Province	
• Participant • Investigator • Outcome assessor • Data analyser		Fars	
Sample size		Postal code	
Target sample size: 60		7185654787	
Randomization (investigator's opinion)		Approval date	
Randomized		2021-09-21, 1400/06/30	
Randomization description		Ethics committee reference number	
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.		IR.SUMS.MED.REC.1400.333	
Blinding (investigator's opinion)		Health conditions studied	
Double blinded		<u>1</u>	
Blinding description		Description of health condition studied	
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		Depression	
		ICD-10 code	
		F32	
		ICD-10 code description	
		Major depressive disorder, single episode	
		<u>2</u>	
		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

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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

Dr. Amir Bazrafshan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Other areas of specialty/work

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Full name of responsible person

Dr. Arash Mansoori

Position

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Latest degree

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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