

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of Add-on Memantine to clonidine on severity of opioid substances (heroin and opium) withdrawal symptoms among opium users

Protocol summary

Study aim

comparing the effect of Add-on Memantine to clonidine on severity of opioid substances (heroin and opium) withdrawal symptoms

Design

Randomized, Double- blind, placebo- controlled clinical trial Addicts who referred are randomly assigning to one of two intervention or control groups (30 person in each group) using randomized block design (equal allocation of time intervals to the intervention and control groups)

Settings and conduct

All drug addicts referred to the outpatient withdrawal center of Khorshid Hospital in Isfahan are randomly divided into two groups of 30 each and treated with memantine or placebo (in addition to co-medications including clonidine and buprenorphine) (routine and current treatment).). The drug administration is double-blind and the evaluator and patient will not be informed of the type of drug. The severity of withdrawal symptoms on days 1, 3, 7, and 21 will be assessed by a resident psychiatrist on a SOWS scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria:DSM-IV criteria for drug dependence.
Exclusion criteria: Non-use of psychiatric drugs and other substances other than cigarettes, Taking pain medications, Comorbid of major psychiatric disorders, Physical illness that is a prohibition on quitting drugs.

Intervention groups

The selected patients divided to two 30 groups.All of them undergoing an as usual treatment with buprenorphine and randomly assigning in 2 groups of memantine and placebo as adding therapy (30 in each group).The severity of withdrawal symptoms in substance dependence on days 1,3,7,21is assessed by Short Opioid Withdrawal Scale(SOWS).

Main outcome variables

Reduce withdrawal symptoms by adding memantine to clonidine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090801002266N11**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2135

Email address

kheirabadi@bsrc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-30, 1398/09/09

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Add-on Memantine to clonidine on severity of opioid substances (heroin and opium) withdrawal symptoms among opium users

Public title
efficacy of memantine on opioid substances withdrawal symptoms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Consent to participate in the study DSM-IV criteria for drug dependence Regular and daily use of opium orally, injectable or smoke
Exclusion criteria:
 Non-use of psychiatric drugs and other substances other than cigarettes Taking pain medications Comorbid of major psychiatric disorders Physical illness that is a prohibition on quitting drugs.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
According to the sample size of 60 people, the samples will be selected in ten blocks of six. Three person in each block will be randomly assigned to the first intervention group and three to the second intervention group, so that all six states of a six-block can be selected ten times randomly from the six blocks. By the end, thirty people will be randomly assigned to each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Study participants receive medication in unnamed drug packages and do not know if the drug is placebo or memantine. The prescribing physician also does not know which patients receive placebo or memantine, and according to the list of random names of patients, the packages named A and B belong to the patients whose names are A and B, and to patients who receive Their names are given in the drug package. Outcome assessor Unaware of the Patient's Drug, assess the severity of withdrawal symptoms using a questionnaire.

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

Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-11-30, 1398/09/09

Ethics committee reference number

IR.MUI.MED.REC.1398.450

Health conditions studied

1

Description of health condition studied

Opioid use disorder

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes

1

Description

severity of opium withdrawal

Timepoint

first, third, 7th, 10th and 21th days

Method of measurement

Short Opioid Withdrawal Scale(SOWS)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group:patients in this groups will be receive Bupronorphine. Bupronorphine dose will be adjusted based on patients need and all of them will be stabilized on Bupronorphine during 3-5 days. Its daily dose is gradually reduced by ten percent per day until

discontinued. Memantine is manufactured by Tesminim Company of Iran and started at a dose of 10 mg daily (5 mg twice daily) as the dose of buprenorphine began to decrease and increased to 20 mg daily (twice daily at 10 mg). And lasts up to three weeks.

Category

Treatment - Drugs

2**Description**

Control group: After discontinuation of the drug, buprenorphine is started in the first dose of 2-4 mg and gradually increased until complete control of withdrawal symptoms, after complete control of withdrawal symptoms with the last dose continued for 3-5 days and then daily dose. Gradually decrease by 10 percent per day until discontinued. Placebo is given to patients in equal numbers in appearance and taste similar to memantine (in collaboration with Isfahan Pharmacy School).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Outpatient Addiction treatment centre of Khorshid Hospital

Full name of responsible person

Gholam Reza kheirabadi

Street address

Behavioral Sciences Research Center, Khorshid hospital., Ostandari Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3222 2475

Email

info@mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo

Street address

HezarJerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

kheirabadi@bsrc.mui.ac.ir

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

Dr Gholam Reza Kheirabadi

Position

Assistant professor of Esfahan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Department of psychiatry of Isfahan University of Medical Sciences , Ostandari Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3222 2475

Email

kheirabadi@bsrc.mui.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Kheirabadi

Position

Assistant professor of Esfahan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Department of psychiatry of Isfahan University of Medical Sciences , Ostandari Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3222 2475

Email

kheirabadi@bsrc.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Kheirabadi

Position

Assistant professor of Esfahan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Department of psychiatry of Isfahan University of Medical Sciences , Ostandari Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3222 2135

Email

kheirabadi@bsrc.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available