

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation the efficacy of Add-on Amantadine to clonidine on severity of opioid withdrawal symptoms.

Protocol summary

Study aim

Determining the effect of adding amantadine to clonidine on improving withdrawal symptoms of opioid 1- Determining and comparing the mean score of the Subjective Scale of Subjective Opioid Withdrawal Scale (SOWS) on days 1, 3, 7, 41 and 21 in the two groups of amantadine + clonidine and placebo + clonidine

Design

The type of this study is phase 3 double-blind clinical trial. The selected patients are assigned to the two treatment groups of clonidine + placebo and clonidine + amantadine in double random blocks. The sample size was calculated for 43 people in each group.

Settings and conduct

Patients referred to the addiction treatment center of Amin Hospital in Isfahan who use opium or heroin and are in the age range of 20-60 years and have DSM-V criteria in terms of substance dependence, by consecutive sampling and observing the inclusion criteria And exit will enter the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Satisfaction to participate in the study 2- Having DSM-V criteria for drug dependence Inclusion criteria: 1. Taking painkillers 2. Existence of major psychiatric disorders (by obtaining a psychiatric history according to DSM-5 criteria) or taking psychiatric medication

Intervention groups

The two intervention and control groups will receive amantadine and clonidine, or placebo and clonidine. In both groups, at the beginning of treatment, opioid is stopped abruptly and buprenorphine at a dose of 2-4 mg is started. The dose is then gradually increased until complete control of withdrawal symptoms. .

Main outcome variables

The process is such that both consecutive eligible entrants are considered as a block. The random mode is such that if the random number is 4-0, it is assigned to group A and if it is 5-9, it is assigned to group B, and

then it is decoded from A and B according to the type of treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090801002266N15**

Registration date: **2021-05-06, 1400/02/16**

Registration timing: **prospective**

Last update: **2021-05-06, 1400/02/16**

Update count: **0**

Registration date

2021-05-06, 1400/02/16

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2135

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of Add-on Amantadine to clonidine on severity of opioid withdrawal symptoms.

Public title

Efficacy of Add-on Amantadine to clonidine on severity of opioid withdrawal symptoms.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction to participate in the study Having DSM-V criteria for drug dependence Regular and daily consumption of opium and heroin orally, injected or smoked

Exclusion criteria:

The patient's unwillingness to continue cooperation
Occurrence of any medical or moral conflict with the continued presence of the patient in the study
Occurrence of physical and mental problems requires special interventions in the management of opioid withdrawal

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Selected patients are randomly assigned to clonidine + placebo and clonidine + amantadine treatment groups. The process is such that both consecutive eligible entrants are considered as a block. The random method is such that if the random number is 4-0, it is assigned to group A and if it is 5-9, it is assigned to group B and then decodes A and B based on the type of treatment (in which drug group each patient was)

Blinding (investigator's opinion)

Double blinded

Blinding description

The intervention and control groups will receive amantadine and clonidine or placebo and clonidine, respectively. The drug is administered in a double-blind manner and the investigator and the patient will not know the type of drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences-School of Medicine

Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-12-14, 1399/09/24

Ethics committee reference number

IR.MUI.MED.REC.1399.1147

Health conditions studied**1****Description of health condition studied**

Severity of opioids withdrawal symptoms

ICD-10 code

F11.20

ICD-10 code description

Opioid dependence, uncomplicated

Primary outcomes**1****Description**

the effects of amantadine in controlling of opioids withdrawal symptoms

Timepoint

The severity of withdrawal symptoms (initial outcome) on the first day (24 hours after the last dose of the drug) as a baseline assessment and then on days 3, 7, 14 and 21

Method of measurement

SOWS scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Clonidine + Amantadine, clonidine made with "drug manufacturing company" in Iran in 0.2

mg tablets and amantadine capsules made in Iran in Hakim Pharmaceutical Company. clonidine will be used in the same manner in both intervention and placebo groups. Amantadine will start with 100 mg daily and will be increased to 100 mg every 12 hours after one week. And Simultaneously with the cessation of the opioids component it will be increased to 300 mg per day (100 mg every 8 hours) and continues for up to three weeks.

Category

Treatment - Drugs

2**Description**

Control group: Clonidine + placebo, clonidine made with "drug manufacturing company" in Iran in 0.2 mg tablets and placebo with similar appearance and taste (prepared in collaboration with Isfahan School of Pharmacy). clonidine will be used in the same manner in both intervention and placebo groups, placebo is also given to patients in the manner of amantadine.

Category

Treatment - Drugs

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

Addiction Treatment Center of Amin Hospital, Isfahan

Full name of responsible person

Gholamreza Kheirabadi

Street address

Amin Hospital, Sanbolistan Alley, Isfahan, Ibn Sina St

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Kheirabadi

Street address

Vice chancellor for research, Isfahan University of Medical Sciences; Faculty of Medicine; Isfahan University of Medical Sciences; Hezar-Jarib Street; Isfahan; Iran

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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

Gholam Reza Kheirabadi

Position

Associate Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

Access range from 1400

To whom data/document is available

All academic researchers

Under which criteria data/document could be used

Analysis other than those listed in the method and research stage is not allowed.

From where data/document is obtainable

Correspondence by e-mail

What processes are involved for a request to access data/document

Request by e-mail with signature and statement of subject

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

Esfahan University of Medical Sciences

Full name of responsible person

Gholam Reza Kheirabadi

Position

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