Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

A comparative study of the effect of a modified method of opioid dependence management with the current method proposed by the Ministry of Health and Medical Education of Iran, on satisfaction, craving and relapse in opioids users.

Protocol summary

Study aim
• Determining and comparing the frequency of discontinuation of treatment in the two groups • Determining and comparing the average number of relapses in the 2 groups • Determining and comparing the average score of substance craving in the 2 groups • Determining and comparing the mean score of patients' satisfaction with detoxification in the 2 groups

Design
Clinical trial with control group, with parallel groups, one-way blinded, randomized, phase 3 on 230 patients.

Settings and conduct
Intervention and control groups from Ariana Addiction Treatment Center, Isfahan; Consecutive sampling through double random, random allocation blocks; Both are eligible within a block and then randomly assigned to one of the study groups. The evaluator who records the data and the patients are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Having Consent 2. DSM-V criteria for addiction 3. Daily use of opium or heroin 4. Not using other substances 5. 20 to 60 years 6. Absence of major psychiatric and physical disorders that are prohibited from withdrawing drugs 7. Not taking psychiatric drugs Exclusion criteria: 1. Any medical or moral conflict with the participation in the study

Intervention groups
Intervention group: In the first three days, clonidine and buprenorphine are administered simultaneously in specific doses. From the 3rd day, in the absence of withdrawal symptoms, clonidine alone is continued. Control group: Method of the Ministry of Health of Iran: Detoxification begins with buprenorphine, continues with a dose reduction of 2 mg every 2 to 3 days and finally stops completely. Initiation of Naltrexone 3 to 5 days after the last dose of buprenorphine.

Main outcome variables
the number of treatment discontinuation; the average score of substance craving .

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090801002266N18**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-02, 1401/05/11**
Update count: **0**

Registration date
2022-08-02, 1401/05/11

Registrant information

Name
Gholamreza Kheirabadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-24, 1401/04/03

Expected recruitment end date
2024-12-23, 1403/10/03

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of a modified method of opioid dependence management with the current method proposed by the Ministry of Health and Medical Education of Iran, on satisfaction, craving and relapse in opioids users.

Public title
Comparison of a modified method of opioid dependence management with the Ministry of Health and Medical Education of Iran method
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study Having DSM-5 criteria for drug dependence Regular and daily consumption of opium or heroin orally, injected or smoked Not using other substances Age 20 to 60 years Absence of major psychiatric disorders and absence of physical illness, which is a ban on withdrawing drugs Not taking psychiatric drugs or any drugs that affects the central nervous system
Exclusion criteria:
The patient's unwillingness to continue cooperation Occurrence of any medical or ethical conflict with the patient's continued participation in the research Occurrence of physical and mental problems requires special interventions in the process of withdrawing drugs Returning to substance abuse in the treatment process
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **230**
Randomization (investigator's opinion)
Randomized
Randomization description
The selection of samples is consecutive sampling and will be continued until the required sample size is completed. The intervention and control group will be selected from the clients of the Ariana addiction treatment center in Isfahan (the original center of the modified addiction treatment method). The samples will be selected into two study groups through double random blocks of random allocation. In this way, both eligible people will be in one block and then they will be randomly assigned to one of the study groups. This process will be continued until reaching the required sample size of 230.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double-blind, so the participants and those responsible for data collection will be blinded. In such a way both the person participating in the study and the evaluator will not know whether the participant belongs to the intervention group or the control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research, School of Medicine, Isfahan University of Medical Sciences
Street address
Behavioral Sciences Research Center, Khorshid Hospital, Ostandari Street
City
Isfehan
Province
Isfehan
Postal code
8145831451
Approval date
2022-04-11, 1401/01/22
Ethics committee reference number
IR.MUI.MED.REC.1401.016

Health conditions studied

1

Description of health condition studied
Detoxification in regular and daily users of opium or heroin orally, injected or smoked
ICD-10 code
F11.23
ICD-10 code description
Opioid dependence with withdrawal

Primary outcomes

1

Description
Instant craving score in the Desires for Drug Questionnaire
Timepoint

The patient will be visited once a week for the first 2 weeks and once every two weeks for several months. After that, the visits are reduced to once a month. At each visit, the patient is examined by a physician.

Method of measurement

Desires for Drug Questionnaire

2

Description

Reduction of cases of withdrawal from treatment

Timepoint

In both groups, data related to cases of non-referral and non-follow-up treatment will be recorded and compared at the end of the intervention and follow-up period.

Method of measurement

Registration in the patient follow-up checklist

3

Description

The level of satisfaction with the detoxification process and the one-year follow-up period

Timepoint

The end of the detoxification period and the end of the one-year follow-up period

Method of measurement

at the end of detoxification period and at the end of one-year follow-up period) in the form of two questions in the text of the questionnaire and using It is measured by the Likert scoring scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: With the onset of withdrawal symptoms, we begin treatment with 0.1 mg of clonidine. Then 2 to 4 mg of sublingual buprenorphine is prescribed (2 mg for amounts less than 3 g of opium or equivalent). If there are symptoms of withdrawal, adjuvant drugs are used and the type and dose used and the reason for administration are recorded accurately. To control restlessness and muscle tension, 10 mg of chlorpheniramine is injected and if not controlled, 5 to 10 mg of diazepam is prescribed.We use 4 to 8 mg of dexamethasone to control pain. On the second day, the patient is evaluated and in the absence of obvious withdrawal symptoms, no intervention is performed, and if there are annoying and obvious withdrawal symptoms, we repeat the steps of the first day.On the third day, the patient is re-evaluated and if the withdrawal symptoms are not severe and annoying, start treatment with clonidine and adjuvants as appropriate and buprenorphine is no longer prescribed, but if the withdrawal symptoms were obvious and annoying on the third day, We prescribe 2 mg of buprenorphine sublingually and re-evaluate after one hour. If symptoms persist, the dose is repeated and treatment with clonidine and other adjuvants will be delayed until the fourth day.The protocol for administering clonidine is as follows: From the third day, in the absence or mild withdrawal symptoms, buprenorphine administration is completely discontinued and clonidine administration is started. If withdrawal symptoms are severe, treatment with clonidine and other adjuvant medications should be started from the fourth day. 0.1 mg of clonidine is given every night before bed and this process will be continued for ten days. If the blood pressure drops to less than 85/55 mm Hg, the next dose of clonidine will be not prescribed, the drug will be reduced and discontinued, and if the hypotension persists for more than 4 hours, clonidine will be discontinued. To assess the severity of withdrawal symptoms and possible complications, the patient will be visited 1 to 3 times a week, the dose of medication is adjusted. Also, the cause and amount of prescribed medications are carefully recorded.To follow up and prevent of recurrency: In the first trimester, patients can visit the doctor freely and whenever they need. In addition, on a weekly basis, they will be invited to the center by phone to talk about their situation during the week and how to manage their cravings. In the second trimester every week and in the next six months every two weeks the patient will be contacted.

Category

Treatment - Drugs

2

Description

Control group: According to the method proposed by the Ministry of Health of Iran for outpatient detoxification with buprenorphine, after that withdrawal symptoms appear, 2 to 5 mg of sublingual buprenorphine will be administered and the patient will be evaluated one hour later. If there are withdrawal symptoms, the dose will be repeated. It should be noted that the maximum dose of administered buprenorphine on the first day is 8 mg. If there are no withdrawal symptoms, the drug is enough for the first day. If there are withdrawal symptoms, adjuvant medications should be used. The type of adjuvant medications, doses and the reason for receiving medications will be carefully recorded. On the second day, the dose of buprenorphine will be increased to 2 to 5 mg. We aim to stabilize the patient as quickly as possible, minimize withdrawal symptoms, and reduce substance consumption. The dose reduction phase begins when the patient stops consumption. The dose reduction phase can be continued from a few days to several weeks. The method of the decrease buprenorphine dose is reducing 1 mg every 2 to 3 days until it is completely stopped, which on average this period will last 2 to 4 days. If withdrawal symptoms worsen during these ten days, the dose should be increased and the reduction process should be slowed down again. In addition, for some symptoms, adjuvant medications (tricyclics, especially amitriptyline, NSAIDs, benzodiazepines, baclofen, antihistamines, antipsychotics, metoclopramide, chlorpromazine, and hyoscine) will be used. The dose and cause of administration are also recorded. At the end of this

detoxification period and 3-5 days after the last dose of buprenorphine is administered, Naltrexone will be started to prevent recurrency. Before starting treatment with naltrexone (according to the Ministry's protocol), the following should be considered: The patient should not have used any opioids during this period. To ensure detoxification, the Naloxone Challenge Test should be performed.This test can be done either intravenously or subcutaneously. 6 mg of naltrexone daily is sufficient to prevent recurrence of opioid use. Naltrexone capsules should be taken as a water-soluble capsule at least for the first few weeks under family supervision and if the patient agrees.The patient will be visited once a week for the first 6 weeks and once every two weeks for several months. After that, the visits are reduced to once a month. At each visit, naltrexone is dissolved in water and in the presence of a physician. Prevention of recurrence with naltrexone will be continued for 6 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ariana Addiction Treatment Center; Isfehan

Full name of responsible person
Dr. Mohammadali Bahramikia

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Unit 413, 4th Floor, Almas Building, Next to the Social Security center, Sharif Crossroads, Imam Khomeini St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
DR. Mansor Siavash, Vice-chancellor for Research of Isfahan University of Medical Sciences

Grant code / Reference number
IR.MUI.MED.REC.1401.016

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
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Position
Professor of Psychiatry, Isfahan University of Medical Sciences

Latest degree
Specialist

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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
There is no further information
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