Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison between clonidine and tizanidine as adjuvant therapy in managing opioid withdrawal syndrome in toxicology icu in Kosar hospital of Karaj and Loghman Hakim hostpital of Tehran

Protocol summary

Study aim
Evaluating the effects of tizanidine and clonidine in adjuvant therapy in withdrawal syndrome management

Design
Two arm parallel group randomized clinical trial with blinded cases. For randomization, the Random allocation software will be used.

Settings and conduct
The place for conducting the research is the toxicology ICUs of Kosar hospital of Karaj and Loghman Hakim hospital of Tehran. Withdrawal syndrome signs will be evaluated using Objective Opioid Withdrawal Scale questionnaire. The patients won't be aware of their group placement.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with history of opioid drug abuse whom urine test verifies that. Exclusion criteria: Acute cardiac disease, other underlying disease, permanent brain damage like encephalopathy

Intervention groups
2 groups: *Methadone and clonidine *Methadone and tizanidine

Main outcome variables
Objective Opioid Withdrawal Scale (OOWS) score; Sedation level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210213050348N1**
Registration date: **2021-05-01, 1400/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-01, 1400/02/11**
Update count: **0**

Registration date
2021-05-01, 1400/02/11

Registrant information

Name
Arman Maghoul

Name of organization / entity
Alborz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between clonidine and tizanidine as adjuvant therapy in managing opioid withdrawal syndrome in toxicology icu in Kosar hospital of Karaj and Loghman Hakim hostpital of Tehran

Public title
Clonidine vs tizanidine for withdrawal syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All the hospitalized patients in toxicology ICU in hospitals Kosar of Karaj and Loghman Hakim of Tehran who are addicted to opioids

Exclusion criteria:

No consent from patient's family

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a number is assigned to each participant and then the numbers are evenly divided into two blocks of clonidine or tizanidine by Random allocation software using simple block randomization method. For this purpose, after installing the program, we determine the number of groups, the sample size and the name of each group. Then, the software places patients with different codes in different groups according to the size of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients who are hospitalized in these wards don't have a high level of consciousness and if the family gives consent, they will enter into the project. In this case the patients and their families won't be aware of the group of the patient. The medicine will be administered without label and with exact similar appearance therefore the patients cannot guess their medicine. The data will be encrypted and the person who analyzes the data won't be aware of the groups of the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, North Taleghani Blvd., Taleghani Sq., Karaj

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2021-02-06, 1399/11/18

Ethics committee reference number

IR.ABZUMS.REC.1399.274

Health conditions studied

1

Description of health condition studied

Opioid withdrawal syndrome

ICD-10 code

F11.23

ICD-10 code description

Opioid dependence with withdrawal

Primary outcomes

1

Description

The Objective Opiate Withdrawal Scale (OOWS)

Timepoint

Evaluating OOWS score in 6, 12, 24, 72 and 120 hours after hospitalization.

Method of measurement

By using OOWS questionnaire

Secondary outcomes

1

Description

Sedation level

Timepoint

6, 12, 24, 72 and 120 hours after hospitalization.

Method of measurement

Recording level and content of consciousness.

2

Description

Length of hospitalization

Timepoint

At the time of discharge

Method of measurement

Patient's charts

Intervention groups

1

Description
Intervention group: Methadone and Tizanidine. Methadone from pharmaceutical company, 5mg q12h. Tizanidine from Aboureyhan pharmaceutical company, 4mg q12h , will be increased upto twice if signs are not relieved. Both will be administered intravenously until the patient is discharged.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar hospital

Full name of responsible person
Hoorvash Faraji Dana

Street address
Kharazmi blvd., Hesarak, Karaj, Iran

City
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3197914795

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2

Recruitment center

Name of recruitment center
Loghman Hakim hospital

Full name of responsible person
Hoorvash Faraji Dana

Street address
Makhsous St., Lashgar intersection, Tehran

City
Tehran

Province
Tehran

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1333635445

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loghman.hospital@sbmu.ac.ir

Web page address
http://lhmc.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Department of Alborz 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
Research Department of Alborz 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
Alborz University of Medical Sciences

Full name of responsible person
Hoorvash Faraji Dana

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Forensic Medicine

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Person responsible for updating data

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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