Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the effectiveness of oral clonidine on pain severity and morphine requirement in patients with orthopedic fractures with history of opioids drug abuse in emergency ward

Protocol summary

Study aim
Effectiveness of oral clonidine on pain intensity and morphine requirement in patients with orthopedic fractures

Design
This double-blind randomized clinical trial study with parallel groups will be conducted on 64 patients with orthopedic fractures referred to Shahid Bahonar Hospital in Kerman. Patients participating in the study will be divided into two groups using a table of random numbers.

Settings and conduct
Patients referred to Shahid Bahoner Kerman Orthopedic Fracture Hospital will be included in the study. Patients participating in the study will be divided into two groups using a table of random numbers. The person participating in the study, the researcher and the person collecting the data will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients referred to Shahid Bahonar Hospital in Kerman with orthopedic fractures who have consented to participate in the study. Non-exclusion criteria: It includes patients who do not have hemodynamic stability and suffer from acute and chronic pain.

Intervention groups
Intervention group 1: will receive 0.2 mg of oral clonidine. Intervention group 2: will receive placebo as a control group.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220822055774N1**
Registration date: **2022-09-20, 1401/06/29**
Registration timing: **prospective**

Last update: **2022-09-20, 1401/06/29**
Update count: **0**

Registration date
2022-09-20, 1401/06/29

Registrant information

Name
Masomeh Nazemirafi

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
2022-11-01, 1401/08/10

Expected recruitment end date
2023-03-02, 1401/12/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effectiveness of oral clonidine on pain severity and morphine requirement in patients with

orthopedic fractures with history of opioids drug abuse in emergency ward

Public title
Clinical trial of the effectiveness of oral clonidine on pain severity and morphine requirement in patients with orthopedic fractures
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old with bone fractures, and pain score >5 based on VASS History of opioid drug abuse Consent to participate in the study
Exclusion criteria:
Pregnancy and breastfeeding women History of underlying cardio-pulmonary, renal diseases high blood pressure Thrombocytopenia Asthma Use of narcotics other than morphine The patient's urgent need for blood transfusion or resuscitation
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked randomization method will be used to allocate samples to intervention and control groups. In this way, an equal number of participants will enter the intervention and control groups at consecutive but equal intervals. Patients in each group will be divided into 6 blocks of 12 people. In this method, one type of treatment is given to the first block and another type to the second and again the first type to the third block and so on. A nurse who was not involved in the study, entered the patients in one of the two groups based on defined blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding in the current study, a double-blind method is used so that 1- the person who checks the results and 2- the person who performs the injections does not know which patient received clonidine and which patient received placebo. to be The person responsible for blinding (emergency nurse) will assign a code (01 to 70) to each patient and record it in the questionnaire. In this way, the intervention group received 0.2 mg of oral clonidine (23) and the control group received the same form of placebo pill. The person responsible for blinding will receive
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences campus, Haft Bagh Alavi, Kerman
City
Kerman
Province
Kerman
Postal code
7616914115
Approval date
2022-09-10, 1401/06/19
Ethics committee reference number
IR.KMU.REC.1401.262

Health conditions studied

1

Description of health condition studied
Bone fracture
ICD-10 code
M96.6
ICD-10 code description
Fracture of bone following insertion of orthopedic implant, joint prosthesis, or bone plate

Primary outcomes

1

Description
Pain
Timepoint
Before the intervention and 30 minutes, 1 hour, 3 hours and 6 hours after the intervention
Method of measurement
Visual pain intensity measurement scale

Secondary outcomes

1

Description

Hemodynamic symptoms (systolic and diastolic blood pressure, heart rate, arterial blood oxygen saturation)

Timepoint

Before the intervention and 30 minutes, 1 hour, 3 hours and 6 hours after the intervention

Method of measurement

Monitoring device

Intervention groups

1

Description

Intervention group 1: will receive 0.2 mg of oral clonidine after entering the emergency room.

Category

Treatment - Drugs

2

Description

Control group: They will receive placebo pills from the person responsible for blinding after entering the emergency room.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Masoume Nazimi Rafi

Street address

Shahid Bahonar Hospital, Qorani St, Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Kerman, at the end of 22 Bahman Blvd., Shahid Bahonar University, Afzalipur Faculty of Medicine

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Zahra Rostamipour

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Assistant professor

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Emergency 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