

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 Bahonar 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

Country

Iran (Islamic Republic of)

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+98 34 3211 2955

Email address

m_nazemi@kmu.ac.ir

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		Placebo	Used
Public title		Assignment	Parallel
Clinical trial of the effectiveness of oral clonidine on pain severity and morphine requirement in patients with orthopedic fractures		Other design features	
Purpose		Secondary Ids	empty
Supportive		Ethics committees	
Inclusion/Exclusion criteria		1	
Inclusion criteria:		Ethics committee	
Patients over 18 years old with bone fractures, and pain score >5 based on VASS History of opioid drug abuse		Name of ethics committee	Ethics Committee of Kerman University of Medical Sciences
Consent to participate in the study		Street address	Kerman University of Medical Sciences campus, Haft Bagh Alavi, Kerman
Exclusion criteria:		City	Kerman
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		Province	Kerman
Age		Postal code	7616914115
From 18 years old		Approval date	2022-09-10, 1401/06/19
Gender		Ethics committee reference number	IR.KMU.REC.1401.262
Both		Health conditions studied	
Phase		1	
2-3		Description of health condition studied	Bone fracture
Groups that have been masked		ICD-10 code	M96.6
- Participant - Investigator - Outcome assessor - Data analyser		ICD-10 code description	Fracture of bone following insertion of orthopedic implant, joint prosthesis, or bone plate
Sample size		Primary outcomes	
Target sample size: 64		1	
Randomization (investigator's opinion)		Description	Pain
Randomized		Timepoint	Before the intervention and 30 minutes, 1 hour, 3 hours and 6 hours after the intervention
Randomization description		Method of measurement	Visual pain intensity measurement scale
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.		Secondary outcomes	
Blinding (investigator's opinion)		1	
Double blinded		Description	
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			

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

City

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Province

Kerman

Postal code

7613747181

Phone

+98 913 493 6949

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

Street address

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

Street address

Afzalipour Faculty of Medicine, Shahid Bahonar University, end of 22 Bahman Blvd, Kerman

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Masoume Nazimi Rafi

Position

Assistant professor

Latest degree

Specialist

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Emergency Medicine

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

General Practitioner

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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