Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of morphine and oxycodone on pain in patients with limb fractures

Protocol summary

Study aim
Determining the effect of morphine and oxycodone on pain in patients with limb fractures

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 92 patients. Block randomization method was used for randomization and block randomization sequence was generated by online software.

Settings and conduct
Valiasr Hospital,Arak,1399. only the in charge specialist of the study is aware of the type of study and study groups, while patients are not aware of the type of prescription drug. Also, the intern only recognizes the groups based on A and B and fills out checklists accordingly. In the first group, 46 patients receive injectable morphine and placebo, and in the second group, 46 patients receive oral oxycodone and injectable placebo. Receipt of medication will be done immediately after transferring the patient to the ward. Patients will then be evaluated for pain intensity based on the VAS ruler before ,30 min,2 and 6 hr after drug administration and pain intensity will be compared. Patients with a VAS score higher than 5 will be excluded from the study..

Participants/Inclusion and exclusion criteria
213/5000 All patients with lower limb fractures (tibia and femur) who are candidates for analgesia after surgery No opioid addiction No history of diabetes and kidney failure No drop in blood pressure, bradycardia and decreased respiratory level

Intervention groups
92 patients are divided into two groups. In the first group, 46 patients received injectable morphine and placebo, and in the second group, 46 patients received oral oxycodone and injectable placebo. Receiving the drug after surgery and after transferring the patient to the ward by the responsible intern will be based on the drugs of groups A and B (previously prepared by the main executor of the project) and without mentioning the name of the drug.

Main outcome variables
pain Intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200708048062N1**
Registration date: **2020-08-10, 1399/05/20**
Registration timing: **prospective**

Last update: **2020-08-10, 1399/05/20**
Update count: **0**

Registration date
2020-08-10, 1399/05/20

Registrant information

Name
Pouria Rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-15, 1399/05/25

Expected recruitment end date
2020-09-05, 1399/06/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of morphine and oxycodone on pain in patients with limb fractures

Public title

The effect of oxycodone on limb fracture pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients whose bone fractures of the lower extremity (tibia and femur) are confirmed by graphic and are candidates for analgesia after surgical treatment. Age between 18 to 60 years

Exclusion criteria:

opioid addiction hypotension, bradycardia, or decreased respiratory rate. history of diabetes and kidney failure.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 92 patients were divided into two completely equal groups using morphine and oxycodone using block randomization method. Block randomization method with quadratic block size was used to divide patients into two groups. In this way, using online software (sealedenvelope), the randomization sequence was generated in a block method and remained with the epidemiologist. Following patient diagnosis and based on the generated randomization sequence, a decision was made to assign individuals to groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the two-sided blindness of the study, in this study, only the relevant specialist in charge of the study (Dr. Solhi, Dr. Azami) is aware of the type of study and the study groups, while patients are of the prescribed drug type. They are not aware. Also, the intern in charge of the project who is in charge of filling out the checklists is not aware of the type of groups based on the prescription drug and only recognizes the groups based on A and B and fills out the checklists accordingly. In the first group, 46 patients receive injectable morphine and placebo, and in the second group, 46 patients receive oral oxycodone and injectable placebo. Receiving the drug after surgery and immediately after transferring the patient to the ward by the responsible intern will be based on group A and B drugs (previously prepared by the main executor of the project) and without mentioning the name of the drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam Complex, Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-07-12, 1399/04/22

Ethics committee reference number

IR.ARAKMU.REC.1399.144

Health conditions studied

1

Description of health condition studied

Tibial fracture

ICD-10 code

S82.1

ICD-10 code description

Fracture of upper end of tibia

2

Description of health condition studied

Tibial fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

3

Description of health condition studied

Tibial fracture

ICD-10 code

S82.3

ICD-10 code description
Fracture of lower end of tibia

4

Description of health condition studied
Femoral bone fracture
ICD-10 code
S72
ICD-10 code description
Fracture of femur

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before the intervention and 30 minutes, 2 hours and 6 hours after the intervention
Method of measurement
Visual Analogue Scale of Pain

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: 46 patients with lower limb fractures (femur and tibia) immediately after surgery and transferred to the inpatient department of morphine sulfate 5 mg intravenously and 2 oral placebo tablets at the same time to control pain Patients with a VAS score above 5 will be treated according to the standard protocol and excluded from the study, and their number will be recorded in the study. Patients were also evaluated for blood pressure and respiratory level and in case of hypotension, bradycardia, decreased respiratory level and bone fractures will be excluded from the study and their number will be recorded in the study.
Category
Treatment - Drugs

2

Description
Intervention group2: 46 patients with lower limb fractures (femur and tibia) Immediately after surgery and transfer to the hospital ward once, 2 oxycodone 5 mg tablets simultaneously and orally and intravenously injectable placebo to control pain Patients with a VAS score above 5 will be treated according to the standard protocol and excluded from the study, and their number will be recorded in the study. Patients were also evaluated for blood pressure and respiratory level and in case of hypotension, bradycardia, decreased respiratory level and bone fractures will be excluded from the study and their number will be recorded in the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Pouria Rezae
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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Street address
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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
Arak 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

Arak University of Medical Sciences

Full name of responsible person

Pouria Rezae

Position

Student

Latest degree

A Level or less

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