

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Fentanyl and Midazolam on pain control and chronic pain prevention in patients with lower limb fracture

Protocol summary

Study aim

the effect of co-injection of Fentanyl and Midazolam on pain control and chronic pain in patients with lower limb fracture referred to Yasuj Shahid Beheshti Hospital

Design

This study is a double-blind clinical trial in 100 male and female trauma patients aged between 30 and 60 years and 100 patients who undergo elective surgery.

Settings and conduct

Patients with hip fractures in Shaheed Beheshti Hospital undergo surgery. Patients are given a completely randomized infusion of fentanyl, 50 micro-grams per hour, and midazolam, 2 milligrams per hour. All patients are monitored for blood pressure, heart rate, oxygen and level of consciousness. To the second group, morphine, 5 to 10 mg, is injected as needed by the stuffs. In the first 24 hours of admission, pain on 5, 15, 24 hours after admission and starting the mentioned drugs are evaluated. In 24 hours after the operation, the patients are evaluated in the same way 5, 15, 24 hours after the operation. Special forms (a modified McGill pain score and visual acuity score scale) that are described to the patient are filled in by the patient. Following the discharge of the patient from the hospital, patients are followed up monthly for 6 months.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients between 30-60 years of age with fractures of the femoral neck that undergo a non-emergency candidate. Patients with a history of diabetes, addiction, blood pressure, or oral intake drugs, or history of chronic pain, are excluded.

Intervention groups

They have femoral bone fractures and are between 30 and 60 years of age, and candidates are acting,

Main outcome variables

Pain control and prevention of chronic pain in patients with lower limb fractures who have taken midazolam and fentanyl inferior compared to patients taking morphine

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20111009007745N10**

Registration date: **2021-09-19, 1400/06/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-19, 1400/06/28**

Update count: **0**

Registration date

2021-09-19, 1400/06/28

Registrant information

Name

Afshin Mansourian

Name of organization / entity

YUMS

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Fentanyl and Midazolam on pain control and chronic pain prevention in patients with lower limb fracture

Public title

The effect of combine fentanyl and midazolam on pain management and prevention of chronic pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

30-60 years old patients with isolated femoral fractures who are not candidated for emergency surgery

Exclusion criteria:

Patients with a history of diabetes, addiction, hypertension, or oral pain relief intake drugs, or history of chronic pain

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants and health care personnel are not aware of the combination of injection drugs and health care personnel will not be involved in choosing patients.

Placebo

Not used

Assignment

Parallel

Other design features

does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Ethics committee of Yasuj University of Medical Sciences ,Motehari Blv, Yasuje, Iran

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Kohgiluyeh-va-Boyerahmad

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7591875114

Approval date

2020-12-16, 1399/09/26

Ethics committee reference number

IR.YUMS.REC.1399.187

Health conditions studied

1

Description of health condition studied

Control of pain and prevention of chronic pain in patients with lower limb fracture

ICD-10 code

S72

ICD-10 code description

Fracture of femur

Primary outcomes

1

Description

Pain control and prevention of chronic pain in patients with lower limb fractures by Fentanyl Infusion and Midazolam

Timepoint

The effect of fentanyl and midazolam infusion on pain management and prevention of chronic pain in patients with lower extremity fracture The patient's pain is evaluated after five hours, 15 hours, 24 hours from the time of admission and starting the infusion drugs. In 24 hours after the operation, the same procedure is measured 5, 15, 24 hours after the operation. After discharge from the hospital, follow-up is done on monthly through with questionnaires mentioned, and all patients were monitored for 6 months

Method of measurement

Based on McGill's Modified Inventory and Visual Analog Scale

Secondary outcomes

1

Description

Quality of life score

Timepoint

Quality of life scores are assessed 1, 3, and 6 months after discharge from the hospital

Method of measurement

Short questionnaire 12 health questions (SF12), designed by War, Kasinski, Keller

Intervention groups

1

Description

Intervention group: Patients with lower limb fractures who are non-emergency candidates for surgery are selected. In the inpatient ward, informed consent is obtained to participate in the study. Numerical pain scale with a range of zero to ten) is given to the patient by the patient with the help of special emoticons describing the pain and a special ruler for this task. Then, at 5, 15 and 24 hours from the time of admission, the patient's pain intensity is evaluated and recorded. Patients are divided into two groups. The group that injects midazolam and fentanyl into the patient by infusion with a pump syringe starts from the time of hospitalization and continues up to 24 hours after the operation. Morphine is injected

Category

Treatment - Drugs

2

Description

Control group: Control of pain in patients with lower limb fractures, these patients are given morphine if needed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Afshin Mansourian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

نشده است

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Afshin Mansourian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Yes - There is 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

Title and more details about the data/document

Unknown

When the data will become available and for how long

Unknown

To whom data/document is available

Unknown

Under which criteria data/document could be used

Unknown

From where data/document is obtainable

Unknown

What processes are involved for a request to access data/document

Unknown

Comments