Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of adding dexmedetomidine to ketorolac and morphine on pain control due to femoral fracture surgery

Protocol summary

Study aim
Comparison of adding dexmedetomidine to ketorolac and morphine on pain control due to femoral fracture surgery

Design
This study is a factorial phase 3 clinical trial that will be conducted in the orthopedic department of Imam Reza Hospital in Tabriz with a sample size of 200 people. The patients will be included in the study by the available sampling method and will be divided into four groups A (dexmedetomidine + morphine), group B (morphine), group C (dexmedetomidine + ketorolac) and group D (ketorolac) using the random number table method.

Settings and conduct
Orthopedic Department of Imam Reza Tabriz Hospital, where only patients will be blinded. The volume of injected medicine will be the same for all patients so that the patients will be blinded during the study. Also, only the relevant nurse will know the type of medicine prepared.

Participants/Inclusion and exclusion criteria
femoral fracture patients will be included in the study regarding the following criteria: consent to participate in the study, candidate for femur fracture surgery, duration of surgery less than 2 hours, body mass index below 30, and spinal anesthesia method and exclusion criteria also include drug addiction, drug use Painkillers half an hour before surgery, amount of bleeding more than 1000 cc during surgery, multi-trauma patients, sensitivity to one of the intervention drugs, history of mental illnesses and use of anti-stress and anti-depressant drugs, history of cardiovascular drug use, patients with a heart rate less than 50 times per minute, patients with heart failure, patients with kidney failure, spinal anesthesia contraindications and patients with a history of deep vein thrombosis.

Intervention groups
They will be divided into four groups A (dexmedetomidine + morphine), group B (morphine), group C (dexmedetomidine + ketorolac) and group D (ketorolac).

Main outcome variables
pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221105056407N1**
Registration date: **2023-03-09, 1401/12/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-09, 1401/12/18**
Update count: **0**

Registration date
2023-03-09, 1401/12/18

Registrant information

Name
Hooman Nateghian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15

Expected recruitment end date
2023-05-05, 1402/02/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of adding dexmedetomidine to ketorolac and morphine on pain control due to femoral fracture surgery

Public title

Comparison of adding dexmedetomidine to ketorolac and morphine on pain control due to femoral fracture surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients undergoing femoral fracture length of the surgery should be under 2 hours Spinal anesthesia should be used

Exclusion criteria:

Patients with BMI of over 30 will be excluded from the study history of addiction to narcotics bleeding more than 1000cc during the surgery multi trauma patients history of anti-anxiety drugs, cardiovascular drugs patients with cardiovascular or renal failure patients with a history of deep vein thrombosis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the random number table method, they will be divided into four groups A (dexmedetomidine + morphine), group B (morphine), group C (dexmedetomidine + ketorolac), and group D (ketorolac). The randomization sequence and allocation concealment (placed in sealed envelopes) were performed by a professor in the absence of the working investigators.

Blinding (investigator's opinion)

Single blinded

Blinding description

The volume of injected medicine will be the same for all patients so that the patients will be blinded during the study. Also, the preparation of medicines in the ward will be done by a skilled nurse and only the relevant nurse will know the type of medicine prepared.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Attar neyshabouri St, Tabriz University of Medical Sciences

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Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.TBZMED.REC.1401.240

Health conditions studied

1

Description of health condition studied

femoral fracture pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain intensity

Timepoint

Pain intensity (measured by Visual Analogue Scale tool) will be measured once every hour for 24 hours.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dexmedetomidine + Morphine

Category

Treatment - Drugs

2

Description
Control group: Morphine
Category
Treatment - Drugs

3

Description
Intervention group: Dexmedetomidine + ketorolac
Category
Treatment - Drugs

4

Description
Intervention group: ketorolac
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada hospital
Full name of responsible person
Behrooz Nazari
Street address
Parastar St, Imam Reza hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Marjan dehdilani
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Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data relating to the investigation conducted in the study will be available.

When the data will become available and for how long
After publishing of the final report

To whom data/document is available
All individuals can request access to the data and files

Under which criteria data/document could be used
People can reanalyze the data and publish it with the permission of the corresponding author

From where data/document is obtainable
Marjan Dehdilani, MD Tabriz Shohada hospital 04133893336 md56422@yahoo.com

What processes are involved for a request to access data/document
The datasets generated during and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Comments