

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 41 3337 3741

Email address

nategh@tbzmed.ac.ir

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

City

tabriz

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

City

tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3389 3336

Email

behrooznazari31@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Bahman Naghipour

Street address

Attar neyshabouri St, Tabriz University of Medical Sciences

City

tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Email

dabirkhanecent@tbzmed.ac.ir

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

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Golestan St, Shohada hospita

City

tabriz

Province

East Azarbaijan

Postal code

629

Phone

+98 41 3389 3336

Email

md56422@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Behrooz Nazari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Golestan St, Shohada hospital

City

tabriz

Province

East Azarbaijan

Postal code

692

Phone

+98 41 3389 3336

Email

behrooznazari31@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

hooman nateghian

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Parastar St, Imam Reza Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Email

hoomannt@gmail.com

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