

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the analgesia effect of Dexmedetomidine with Fentanyl, in combination with Marcaine in femoral neck fracture surgery with spinal anesthesia

Protocol summary

Study aim

Determining and comparing the analgesia effect of Dexmedetomidine with Fentanyl, in combination with Marcaine in femoral neck fracture surgery with spinal anesthesia, in medical centers-hospital of Qazvin University of Medical Sciences.

Design

A double-blind clinical trial with a control group, with parallel groups, non-random allocation, phase 3, the number of 25 samples in each group is estimated. Allocation of samples to intervention groups is done based on doctor's diagnosis

Settings and conduct

This study is conducted in patients with femoral neck fractures referred to Rajai educational and therapeutic centers who are candidates for femoral neck fracture surgery according to the order of the orthopedic surgeon. With the doctor's diagnosis the patient entered one of the three test groups A (Marcaine-Fentanyl), the experiment B (Marcaine-Dexmedetomidine) and control group (placebo). The dose of drugs is: (25µg/kg Fentanyl), (2.5mg/kg Marcaine) and (5µg/kg Dexmedetomidine) The participant and outcome evaluator are blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 45 to 75 who come to Shahid Rajaei Hospital with a complaint of femoral neck fracture exclusion criteria: Taking corticosteroids, antihistamines and painkillers for a long time Hypersensitivity to marcaine, fentanyl and dexmedetomidine

Intervention groups

Test group A (Marcaine - Fentanyl), Test group B (Marcaine - Dexmedetomidine) and control group (placebo) Dosage of drugs: Fentanyl 25µg/kg, Marcaine 2.5mg/kg and Dexmedetomidine 5µg/kg

Main outcome variables

The amount and intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230805059046N1**

Registration date: **2023-09-03, 1402/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-03, 1402/06/12**

Update count: **0**

Registration date

2023-09-03, 1402/06/12

Registrant information

Name

Paria Talebnezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesia effect of Dexmedetomidine with Fentanyl, in combination with Marcaine in femoral neck fracture surgery with spinal anesthesia

Public title

"Comparison of the effect of Dexmedetomidine + Marcaine with Fentanyl + Marcaine in femur fracture surgery"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in research with informed consent after giving necessary and sufficient explanations about the study The person's age should be between 45 and 75 years No history of surgery No history of smoking, alcohol and drugs Not having chronic physical or mental illness (schizophrenia, diabetes, etc.) Not having vision and hearing problems and other disabilities Not using corticosteroids, antihistamines, narcotics and painkillers for a long time Lack of allergy to marcaine, fentanyl and dexmedomidine Absence of pregnancy, breastfeeding and abortion less than 3 months

Exclusion criteria:

Unwillingness to cooperate in the study Occurrence of any problems and complications during the study The diagnosis of the surgeon or other specialists to withdraw from the study Heart diseases and HTN Liver diseases (cirrhosis, hepatitis, etc.)

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

This is a double-blind type of experiment, which will be blind for the people participating in the study and evaluating the outcome. In the consent form to participate in the study, it is written for the patient that his presence does not necessarily mean intervention but may be included in the control group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of qazvin University of Medical Sciences

Street address

Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd,Qazvin

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Province

Qazvin

Postal code

3413996134

Approval date

2022-03-12, 1400/12/21

Ethics committee reference number

IR.QUMS.REC.1400.489

Health conditions studied**1****Description of health condition studied**

Femoral neck fracture surgery

ICD-10 code

S72.0

ICD-10 code description

Fracture of head and neck of femur

Primary outcomes**1****Description**

The amount and intensity of pain

Timepoint

3, 6 and 12 hours after the operation

Method of measurement

Using a ruler-like grading system (Visual Analog Scale) from 0 (no pain) to 10 (the most severe pain imaginable)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group A: (25 µg/kg Fentanyl from Caspian Tamin Pharmaceutical Company and 2.5 mg/kg Marcaine

from Adorateb Pharmaceutical Company). After patients enter the operating room, anesthesia is started with spinal anesthesia, and the anesthesiologist starts prescribing Marcaine-Fentanyl.

Category

Treatment - Drugs

2

Description

Intervention group B: (5µg/kg Dexmedetomidine from Exir Pharmaceutical Company and 2.5mg/kg Marcaine from Adorateb Pharmaceutical Company). After patients enter the operating room, anesthesia is started with spinal anesthesia and the anesthesiologist prescribes Markain-Dexmedetomidine.

Category

Treatment - Drugs

3

Description

Control group: Routine hospital anesthesia method (2.5mg/kg Marcaine from Adorateb Pharmaceutical Company). After patients enter the operating room, anesthesia is started with spinal anesthesia and the anesthesiologist prescribes Markain

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Paria Talebnezhad

Position

Resident

Latest degree

Medical doctor

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

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