

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of dexamethasone on antiemetic use after pelvic and femoral surgery in patients

Protocol summary

Study aim

1. Determining the frequency distribution of the studied population based on demographic characteristics 2. Determining and comparing the average glycosylated hemoglobin before and after hip and femur surgery in two groups 3. Determining and comparing the frequency and type of drug use before and after hip and femur surgery in two groups 4. Determining and comparing the type of surgery of patients in hip and femur surgeries in two groups 5. Determining and comparing the average scores of pain, nausea and vomiting, equivalent consumption of morphine, use of antiemetics, use of Andasterone at 4-hour intervals after hip and femur surgeries in two groups 6. Determining and comparing the average length of stay in the hospital after hip and femur surgery in two experimental and control groups.

Design

Clinical trial with a control group, three blinded, randomized, on 140 patients who were used for randomization from groups A and B.

Settings and conduct

The study population is people admitted for hip and femur surgery in Imam Khomeini Hospital in 2022. Before the operation, patients in both groups will receive a single oral dose of acetaminophen 1000 mg and pregabalin 100 mg. In the intervention group, patients will receive 10 mg of dexamethasone intravenously in 90 minutes after surgery.

Participants/Inclusion and exclusion criteria

Patients over 18 years old in 2022 who undergo hip and femur surgery were defined. Exclusion criteria include: patients undergoing surgery, or having a history of recent pregnancy, using steroid or immunosuppressive drugs within 6 months after kidney or liver surgery, and having drug and alcohol abuse.

Intervention groups

Intervention Patients will receive 10 mg of dexamethasone intravenously in 90 minutes after surgery.

Main outcome variables

Reducing narcotics and reducing pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181112041616N2**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dexamethasone on antiemetic use after pelvic and femoral surgery in patients

Public title

The effect of dexamethasone on antiemetics

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients over 18 years old in 2022 who undergo hip and femur surgery

Exclusion criteria:

Patients who are undergoing surgery or have a recent history of pregnancy, use steroid or immunosuppressant drugs within 6 months after kidney or liver surgery, and have drug and alcohol abuse.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

A code of 1 to 140 is considered for each questionnaire. And the random assignment is that we consider two groups named A and B, after that we put even numbers in group A and odd numbers in group B, and finally one group is called intervention and the other group. We consider it as control.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, principal investigator, physicians, nurses, orthopedic surgeons, data collection and outcome assessors, and the data safety and monitoring committee.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

کمیته اخلاق دانشگاه علوم پزشکی جیرفت

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Approval date

2023-08-27, 1402/06/05

Ethics committee reference number

IR.Jmu.Rec. 1402.025

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

Hip and femur surgery

ICD-10 code

M95-M99

ICD-10 code description

Other acquired deformities of musculoskeletal system and connective tissue

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

Pain score scale, use of antiemetic drug after surgery

Timepoint

Oxycodone 5 mg orally every 12 hours for moderate pain and 4 mg of ondansetron postoperatively every 4-6 hours to control nausea and vomiting.

Method of measurement

Oxycodone 5 mg orally every 12 hours for moderate pain and 4 mg of ondansetron postoperatively every 4-6 hours to control nausea and vomiting.

Secondary outcomes

empty

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

Intervention group: Before the operation, patients in both groups will receive a single oral dose of acetaminophen 1000 mg and pregabalin 100 mg. In the intervention group, patients will receive 10 mg of dexamethasone intravenously in 90 minutes after surgery. A local infiltration cocktail of 62 ml was injected during the

operation, which consists of the following drugs: Also, in both groups, all patients during the first 24 hours after the operation, (3 mg/kg and the maximum dose of 300 mg, 60 ml) 0.5% ropivacaine, will receive 30 mg (1 ml) of ketorolac and 5 mac/kg of epinephrine. Analgesics: acetaminophen 1000 mg orally every 8 hours, oxycodone 5 mg orally every 12 hours as needed for moderate pain or 10 mg for severe pain, meloxicam 7.5 mg orally every 12 hours, gabapentin 100 mg orally every 12 hours and diazepam 5 mg orally as needed for muscle spasms. In addition, patients in both groups will receive more opioid analgesics as needed. If necessary, intravenous doses of four milligrams of ondansetron will be prescribed every 4-6 hours to control post-operative nausea and vomiting (PONV). Prochlorperazine will be used as a secondary antiemetic. Complications such as readmission, infection, reoperation, dislocation, venous thrombosis, pulmonary embolism, pneumonia and other post-operative cases are also investigated. To collect medical records information: age, sex, body mass index, type of surgery, smoking status, diabetes status and measurement of glycosylated hemoglobin less than 3 months before surgery will be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان امام خمینی

Full name of responsible person

دکتر سینا حیدری

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jeeroft University of Medical Sciences

Full name of responsible person

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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

Jeeroft 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

Jeeroft University of Medical Sciences

Full name of responsible person

دکتر سینا حیدری

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Master's Degree in Epidemiology - Hospital Research
Officer

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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