Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effects of Two Different Doses of Remifentanil Infusion on Intraoperative Blood Loss and Hemodynamic Parameters in Patients Undergoing Femur Surgery

Protocol summary

Study aim

To compare the effects of two different doses of remifentanil infusion (0.25 and 0.5 mcg/kg/min) on intraoperative blood loss and hemodynamic changes in patients undergoing femur surgery.

Design

A randomized, double-blind, parallel-group, controlled clinical trial with 1:1 allocation ratio on 60 patients undergoing femur surgery. Random Allocation software was used for randomization.

Settings and conduct

The study will be conducted at Shahid Mohammadi Hospital in Bandar Abbas. After obtaining informed consent, 60 patients will be randomly allocated. Hemodynamic parameters will be recorded every 15 minutes. For postoperative pain with a visual analogue scale greater than 3, pethidine will be administered.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 70 years who are candidates for elective femur surgery under general anesthesia with ASA class I and II will be included. Exclusion criteria include severe cardiovascular diseases, remifentanil allergy, lack of informed consent, and need for additional morphine during surgery.

Intervention groups

Group one receives remifentanil 0.25 mcg/kg/min and group two receives 0.5 mcg/kg/min. All patients receive identical anesthesia induction with midazolam, fentanyl, propofol, and atracurium plus morphine sulfate 0.1 mg/kg.

Main outcome variables

Primary outcomes include intraoperative blood loss and hemodynamic parameters (systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate). Secondary outcomes include blood transfusion requirements, fluid consumption, surgeon satisfaction, postoperative pain intensity, analgesic requirements, and urine output.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240929063203N3**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **prospective**

Last update: **2025-11-18, 1404/08/27**
Update count: **0**

Registration date

2025-11-18, 1404/08/27

Registrant information

Name

Milad Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 9999 4691

Email address

miladmohammadi981@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Effects of Two Different Doses of Remifentanil Infusion on Intraoperative Blood Loss and Hemodynamic Parameters in Patients Undergoing Femur Surgery

Public title
Comparison of Two Different Doses of Remifentanil on Bleeding and Hemodynamics in Femur Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals aged 18 to 70 years Candidates for femur surgery Undergoing general anesthesia No use of opioid analgesics before surgery No history of allergy or hypersensitivity to remifentanil or similar drugsRetry

Exclusion criteria:
Diagnosis of serious diseases or medical conditions that may affect the study outcomes (such as severe cardiovascular disorders or bradycardia) Allergy or severe hypersensitivity reaction to the medications used in the study. Lack of informed consent or withdrawal of the patient from the study at any stage of the research. If patients require additional morphine during the procedure.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this clinical trial, simple block randomization with individual randomization units will be used. Patients aged 18 to 70 years with ASA class I and II who are candidates for femur surgery under general anesthesia will be placed in blocks of 4 and 6 individuals and assigned in a 1:1 ratio to two groups: low-dose (0.25 mcg/kg/min) and high-dose (0.5 mcg/kg/min) remifentanil. Random Allocation Software will be used to generate the random sequence, with sealed opaque envelopes as a backup method. The seed number will be extracted from the system time at execution and recorded for reproducibility. Allocation concealment will be ensured through a central system that does not reveal allocation until complete patient information is registered, unique coding for each patient, separation of research team responsibilities (separation of enrollment personnel from allocation personnel), emergency envelopes for urgent cases, restricted access control to the randomization sequence, and complete process documentation to minimize selection bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind clinical trial in which patients, surgeons, surgical team, and outcome assessors will be unaware of the remifentanil dose administered (0.25 or 0.5 µg/kg/min) and the patient's group allocation. Drug preparation and administration will be performed by an anesthesiologist who is not involved in outcome assessment, and syringes containing remifentanil will be prepared with coded labels (A or B) without indicating the actual dose. Allocation codes will be kept in sealed envelopes and will not be opened until the end of the study and completion of data analysis, except in emergency situations. Data collection will be performed by a nurse or research assistant who is blinded to patient grouping, and only the anesthesiologist responsible for drug preparation and the person responsible for randomization (who are not involved in enrollment and outcome assessment) will be aware of the allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Hormozgan University of Medical Sciences

Street address
Shahid Chamran Boulevard, University of Medical Sciences and Health Services, Bandar Abbas.

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Bandar Abbas

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Postal code
7916613885

Approval date
2025-08-19, 1404/05/28

Ethics committee reference number
IR.HUMS.REC.1404.179

Health conditions studied

1

Description of health condition studied
Surgery

ICD-10 code

Z47.82

ICD-10 code description

Encounter for orthopedic aftercare following scoliosis surgery

Primary outcomes

1

Description

Volume of blood loss during femur surgery measured in milliliters

Timepoint

Measured continuously during the surgery from the start of the surgical incision until wound closure

Method of measurement

Measurement of blood volume collected in suction containers and blood-soaked surgical gauzes during surgery

2

Description

Systolic blood pressure measured in millimeters of mercury during femur surgery

Timepoint

Measured at baseline (before anesthesia induction) and at 15-minute intervals during surgery

Method of measurement

Non-invasive blood pressure monitoring device (automated sphygmomanometer)

3

Description

Diastolic blood pressure measured in millimeters of mercury during femur surgery

Timepoint

Measured at baseline (before anesthesia induction) and at 15-minute intervals during surgery

Method of measurement

Non-invasive blood pressure monitoring device (automated sphygmomanometer)

4

Description

Mean arterial pressure measured in millimeters of mercury during femur surgery

Timepoint

Measured at baseline (before anesthesia induction) and at 15-minute intervals during surgery

Method of measurement

Calculated automatically by non-invasive blood pressure monitoring device using the formula: MAP = DBP + 1/3(SBP - DBP)

5

Description

Heart rate measured in beats per minute during femur surgery

Timepoint

Measured at baseline (before anesthesia induction) and at 15-minute intervals during surgery

Method of measurement

Electrocardiogram (ECG) monitoring device and pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients undergoing elective femur surgery under general anesthesia will receive intravenous remifentanil infusion at a dose of 0.25 micrograms per kilogram per minute. The infusion will start after anesthesia induction and continue until the end of surgery. Anesthesia induction protocol includes: Midazolam 0.1 mg/kg, Fentanyl 2 micrograms/kg, Propofol 2 mg/kg, and Atracurium 0.5 mg/kg. All patients will also receive Morphine Sulfate 0.1 mg/kg intraoperatively for analgesia. Drug name: Remifentanil (as Ultiva or equivalent), Route of administration: Continuous intravenous infusion, Dose: 0.25 µg/kg/min, Duration: From anesthesia induction until end of surgery.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients undergoing elective femur surgery under general anesthesia will receive intravenous remifentanil infusion at a dose of 0.5 micrograms per kilogram per minute. The infusion will start after anesthesia induction and continue until the end of surgery. Anesthesia induction protocol includes: Midazolam 0.1 mg/kg, Fentanyl 2 micrograms/kg, Propofol 2 mg/kg, and Atracurium 0.5 mg/kg. All patients will also receive Morphine Sulfate 0.1 mg/kg intraoperatively for analgesia. Drug name: Remifentanil (as Ultiva or equivalent), Route of administration: Continuous intravenous infusion, Dose: 0.5 µg/kg/min, Duration: From anesthesia induction until end of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Great Prophet's (PBUH) educational, therapeutic and research center

Full name of responsible person

Milad Mohammadi

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hormozgan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Still undecided - no release schedule yet.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable