# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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**

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Iran (Islamic Republic of)

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**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.

**City**
Bandar Abbas

**Province**
Hormozgan

**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**
**Name of organization / entity**
Bandare-abbas 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?**
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**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Mehrdad Malekshoar
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

Student

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Bachelor

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Anesthesiology

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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