Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparing the effects of Propofol and Propofol-Ketamine anesthesia maintenance regime on hemodynamic parameters during anesthesia and postoperative complications in patients undergoing leg fracture surgery

Protocol summary

Summary

(1)Objectives: Comparison of the effects of two anesthesia maintenance regime on hemodynamic parameters during anesthesia and postoperative complications in patients with leg fracture.(2)Design: The study was performed as randomized double-blind clinical trial on 94-95 on 60 patients who candidate for surgery and trial phase was 3. (3)setting and conduct:Patients were randomly divided to Propofol or Propofol – Ketamine group.All patients were anesthetized with 2mg/kg Propofol, 5µg/kg Fentanyl, and 0.5 mg/kg Atracurium after which one group of patients received Propofol (100 µg/kg/min) and the other group received a combination of Propofol Ketamine(50µg/kg/min Propofol and 25µg/kg/min Ketamine).(4)participants including major eligibility criteria:Patients who were candidate for leg fracture surgery with class 1 and 2 ASA and aged 15 to 45 years old entered the study.Patients who had addiction and had a history of motion disease were excluded.(5)interventtion: use of 2mg/kg Propofol, 5µg/kg Fentanyl, and 0.5 mg/kg Atracurium in both group for induction and use of Propofol 100 µg/kg/min in one group and of Propofol Ketamine combination (50µg/kg/min Propofol and 25µg/kg/min Ketamine) in another group for maintenance regime . (6)main outcome measures: Heart rate, systolic and diastolic blood pressure, and MAP recorded when the patient is lying on the bed before induction, one minute after induction,after laryngoscopy and intubation and then in 10-minute intervals to the end of the procedure.Pain, nausea and vomiting after the patients were conscious up to 6 hours after the patient is sent out of recovery in 2-hour intervals using VAS criterion measured and analysised.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062222867N1**
Registration date: **2016-09-10, 1395/06/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-10, 1395/06/20

Registrant information

Name

Bibi Fatemeh Shakhs Emampour

Name of organization / entity

Birjand University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3244 3001

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology affairs of Birjand University of Medical Sciences (BUMS)

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effects of Propofol and Propofol-Ketamine anesthesia maintenance regime on hemodynamic parameters during anesthesia and postoperative complications in patients undergoing leg fracture surgery

Public title
Comparing the effects of two anesthesia maintenance regime on hemodynamic parameters during anesthesia and postoperative complications

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:Patients between 15-45 years old; Class 1 and 2 ASA; Candidate for leg fracture surgery.
Exclusion criteria:History of recent upper respiratory tract infection; Asthma; Allergy (to Propofol-Ketamine, eggs, and soya);Taking antipsychotic drugs; Neuromuscular diseases ; Epilepsy; Acid reflux; Hiatal hernia; Severe anemia; Severe liver diseases; Severe heart diseases; Severe lung diseases; Drugs addiction; A history of motion disease; Migraine

Age
From **15 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Birjand University of Medical Sciences

Street address
Birjand University of Medical Sciences, Ghafari St

City
Birjand

Postal code

Approval date
2014-11-30, 1393/09/09

Ethics committee reference number
IR.BUMS.1393.903

Health conditions studied

1

Description of health condition studied
Leg fracture

ICD-10 code
S82.8

ICD-10 code description
Fractures of other parts of lower leg

Primary outcomes

1

Description
Heart Rate

Timepoint
Before induction, one minute after induction, after laryngoscopy and intubation, and then in 10-minute intervals to the end of the surgery

Method of measurement
Heart monitoring

2

Description
Systolic blood pressure

Timepoint
Before induction, one minute after induction, after laryngoscopy and intubation, and then in 10-minute intervals to the end of the surgery

Method of measurement
Heart monitoring

3

Description
Diastolic blood pressure

Timepoint
Before induction, one minute after induction, after laryngoscopy and intubation, and then in 10-minute intervals to the end of the surgery

Method of measurement
Heart monitoring

4

Description
Mean arterial pressure

Timepoint
Before induction, one minute after induction, after laryngoscopy and intubation, and then in 10-minute intervals to the end of the surgery

Method of measurement

Heart monitoring

Secondary outcomes

1

Description
pain
Timepoint
After anesthesia is finished up to 6 hours after going out of recovery in 2-hour intervals
Method of measurement
Visual Analogue Scale (VAS)

2

Description
nausea
Timepoint
After anesthesia is finished up to 6 hours after going out of recovery in 2-hour intervals
Method of measurement
Visual Analogue Scale (VAS)

3

Description
vomiting
Timepoint
After anesthesia is finished up to 6 hours after going out of recovery in 2-hour intervals
Method of measurement
Visual Analogue Scale (VAS)

Intervention groups

1

Description
First group: Induction 2mg/kg of Propofol, 5µg/kg of Fentanyl, and 0.5 µg/kg of Atracurium and maintenance regime 100 µg/kg/min Propofol
Category
Treatment - Drugs

2

Description
Second group:Induction 2mg/kg of Propofol, 5µg/kg of Fentanyl, and 0.5 µg/kg of Atracurium and maintenance regime 50 µg/kg/min of Propofol + 25 µg/kg/min Ketamine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Birjand Imam Reza Hospital
Full name of responsible person
Dr. Bibi Fatemeh Shakhs Emampour
Street address
Orthopedic operating room, Imam Reza Hospital
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Birjand University of Medical Sciences
Full name of responsible person
Gholamreza Sharifzadeh
Street address
Birjand University of Medical Sciences, Ghafari St
City
Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Birjand University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Bibi Fatemeh Shakhs Emampour
Position
Anesthesiologist, Assistant professor of Birjand University of Medical Sciences
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty