

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 analysed.

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

fatemeh.emampour@bums.ac.ir

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

Street address

Birjand University of Medical Sciences, Ghaffari st

City

Birjand

Postal code

Phone

+98 56 3244 3001

Fax

+98 56 3244 5402

Email

f.emempour@gmail.com

Web page address

Person responsible for scientific 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

Street address

Birjand University of Medical Sciences, Ghaffari st

City

Birjand

Postal code

Phone

+98 56 3244 3001

Fax

+98 56 3244 5402

Email

f.emampour@gmail.com

Web page address

Person responsible for updating data

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

Street address

Birjand University of Medical Sciences, Ghaffari st

City

Birjand

Postal code

Phone

+98 56 3244 3001

Fax

+98 56 3244 5402

Email

f.emampour@gmail.com

Web page address

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