

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative Evaluation of Ketamine-Fentanyl and Propofol-Fentanyl on Hemodynamic Changes of Laryngeal Mask Airway Insertion and Post Anesthesia Complications in Inguinal Herniorrhaphy Surgery

Protocol summary

Summary

To compare the effects of Propofol-Fentanyl and Ketamine-Fentanyl on hemodynamic changes during Laryngeal Mask Airway insertion and post anesthesia complications in Inguinal Herniorrhaphy surgery, in a clinical trial, 120 patients aged 16 to 70 who are candidate for Herniorrhaphy surgery are included. The patients are randomly divided in two groups: Group A (Ketamine-Fentanyl) and Group B (Propofol-Fentanyl). In group A Fentanyl 3 µ/kg and Ketamine 2 mg/kg, and in group B Fentanyl 3 µ/kg and Propofol 2 mg/kg, will be intravenously injected, then an appropriate Laryngeal Mask Airway will be inserted. Anesthesia will be continued in both groups using mechanical ventilation with 50 % N2O - 50% O2 and Isoflurane 1.2%. Heart Rate and Blood Pressure, will be recorded before the induction of anesthesia and insertion of Laryngeal Mask Airway, and 1, 3, 5 and 10 minutes after it. Duration of surgery and recovery, agitation, nausea and vomiting will also be recorded in order to compare between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070618375N1**

Registration date: **2014-09-14, 1393/06/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-14, 1393/06/23

Registrant information

Name

Mohamad Hajjafari

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of Ketamine-Fentanyl and Propofol-Fentanyl on Hemodynamic Changes of Laryngeal Mask Airway Insertion and Post Anesthesia Complications in Inguinal Herniorrhaphy Surgery

Public title

Comparing the effects of Ketamine-Fentanyl and Propofol-Fentanyl on Anesthesia Process

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who are candidate for Herniorrhaphy surgery
Exclusion Criteria: Hemodynamic instability; History of psychotic disorder; Brain injury or

intracranial lesion; ASA class 3 or more; History of reaction to anesthetic drugs

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Panzdah Khordad Square, Kashan

City

Kashan

Postal code

Approval date

2014-06-11, 1393/03/21

Ethics committee reference number

1474

Health conditions studied

1

Description of health condition studied

Hemodynamic changes during insertion of Laryngeal Mask Airway and post anesthesia complications after using Ketamine-Fentanyl and Propofol-Fentanyl

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vomiting

Timepoint

During the recovery

Method of measurement

Observation

2

Description

Agitation

Timepoint

During the recovery

Method of measurement

Richmond Agitation Sedation Scale (RASS)

3

Description

Heart Rate

Timepoint

1, 3, 5, 10 min

Method of measurement

Beat per minute

4

Description

Blood Pressure

Timepoint

1, 3, 5, 10 min

Method of measurement

mm Hg

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Fentanyl 3 µ/kg and after 3 minutes Ketamine 2 mg/kg, Atrachorium 0.3 mg/kg is intravenously injected and after 3 minutes appropriate Laryngeal Mask Airway is inserted.

Category

Treatment - Drugs

2

Description

Control Group: Fentanyl 3 µ/kg and after 3 minutes Propofol 2 mg/kg, Atrachorium 0.3 mg/kg is injected and after 3 minutes appropriate Laryngeal Mask Airway is inserted.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

Mohammad Hajijafari

Street address

Ravand Boulevard

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamidi

Street address

Ravand Boulevard

City

Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Hajijafari

Position

Anesthesiologist

Other areas of specialty/work

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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