

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of remifentanyl effect on hemodynamic responses to arrange LMA in anesthesia induction with propofol and fentanyl or ketamine

Protocol summary

Study aim

Determining the effect of remifentanyl on hemodynamic response to laryngeal mask airway insertion in induction of anesthesia with propofol in combination with fentanyl or ketamine

Design

This study is a double-blind randomized clinical trial performed on 44 patients undergoing cataract surgery. Patients using Random allocation software will be allocated to two groups receiving fentanyl-propofol and ketamine-propofol. Remifentanyl is given at the same time in both groups.

Settings and conduct

In this study, the effect of remifentanyl on hemodynamic response to laryngeal mask airway insertion induction of anesthesia with propofol combined with fentanyl and ketamine is evaluated in cataract surgery. The patient, anesthesiologist, and data collector are unaware of the drug grouping. Patients are randomly assigned to one of the two groups of fentanyl 1 mcg/kg and ketamine 0.5mg / kg. Propofol 1mg / kg and remifentanyl 0.5mcg / kg will be prescribed in both. The study site is Faiz Hospital in Isfahan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA class I and II candidates for cataract surgery with aged 30 to 85 years
Non-inclusion criteria: Poor mouth opening Pharyngeal pathology Laryngeal pathology Pulmonary diseases Risk of aspiration (full stomach, gastroesophageal reflux disease, pregnancy) History of allergy to any anesthetic drugs High airway resistance

Intervention groups

Two intervention groups: The first group received propofol 1mg / kg, fentanyl 1µ / kg and remifentanyl 0.5mcg / kg The second group received propofol 1mg / kg, ketamine 0.5mg / kg and remifentanyl 0.5mcg / kg.

Main outcome variables

Heart rate, systolic blood pressure, diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N14**

Registration date: **2020-09-20, 1399/06/30**

Registration timing: **retrospective**

Last update: **2020-09-20, 1399/06/30**

Update count: **0**

Registration date

2020-09-20, 1399/06/30

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

2020-04-19, 1399/01/31

Actual recruitment end date

2020-07-21, 1399/04/31

Trial completion date

2020-07-21, 1399/04/31

Scientific title

Study of remifentanil effect on hemodynamic responses to arrange LMA in anesthesia induction with propofol and fentanyl or ketamine

Public title

Study of remifentanil effect on hemodynamic responses to arrange LMA

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Class I and II ASA patients Candidate for cataract surgery under general anesthesia Adults (30 to 85 years)

Exclusion criteria:

Patient dissatisfaction, Weight less than 40 or more than 110 kg, Existence of cervical vertebrae,

Age

From **30 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals are randomly assigned to two intervention groups and assigned using Random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient, surgeon, anesthesiologist, and observer of the results were unaware of the grouping of patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Blvd, Isfahan University of Medical

Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

IR.MUI.MED.REC.1397.286

Health conditions studied

1

Description of health condition studied

Cataract surgery

ICD-10 code

Z98.4

ICD-10 code description

Cataract extraction status

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before induction of anesthesia, immediately before laryngeal mask implantation and at 1, 3 and 5 minutes after LMA placement and fixation

Method of measurement

Mercury sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: Ventanil, in this group, syringes containing 1 mg / kg propofol and 1μ / kg fentanyl are injected into people.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 2: Ketamine, in this group, the syringe contains 1 mg / kg propofol and 0.5 mg / kg ketamine for injection in individuals.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital

Full name of responsible person

Hamidreza Shetabi

Street address

Feyz Hospital , Modares St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaqayeq haqjou javanmard

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Vice chancellor of research and technology of
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences

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Position

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available