

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Study of remifentanyl effect on hemodynamic response 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 1 $\mu$  / 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 ketamin

#### 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 1 $\mu$  / 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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3445 2034

**Email**

Hamidshetabi@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

shaqayeq haqjou javanmard

**Street address**

Vice chancellor of research and technology of university. Isfahan University of Medical Sciences.  
Hezarjarib St

**City**

isfahan

**Province**

Isfahan

**Postal code**

۷۳۴۶۱-۸۱۷۴۶

**Phone**

+98 31 3668 5149

**Email**

sh\_haghjoo@med.mui.ac.ir

**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

**Street address**

Faiz Hospital, Modares St

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8817976155

**Phone**

+98 31 3620 2020

**Fax****Email**

Hamidshetabi@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

Associate professor

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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