

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Comparison of the effect of fentanyl-propofol and pethidine-propofol on the sedation level during cataract surgery by phacoamulsification method

#### Protocol summary

##### Study aim

Determination of the Effect of Fentanyl Propofol Combination with Peptidine-Propofol on the Relaxation Level during Phacoamulsification

##### Design

Clinical trials in two community-based and pragmatic groups with parallel groups, a total volume of 80, double blinded, and randomized

##### Settings and conduct

The use of two different drugs with specific doses in two groups and comparing their effect on the sedation level in cataract surgery by phacoamulsification in Feyz Hospital in Isfahan. The patient and Researcher unaware of which drugs are used for each patient.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18 to 90 years undergoing cataract surgery using phacoemulsification methods under local anesthesia and sedation in the first and second classes of the American Anesthetic Association. Exclusion criteria: history of any allergy to the drug used in the design, history of drug addiction, alcohol, benzodiazepine and pregnancy, congestive heart failure, history of head trauma, glaucoma, hypotension, evidence of increased intracranial pressure, psychosis, schizophrenia, active upper respiratory tract infection, Asthma, chronic respiratory disease.

##### Intervention groups

First intervention group: Combination of fentanyl-propofol and Second intervention group: combination of pethidine propofol to measure sedation levels in comparison with other drugs used in cataract surgery

##### Main outcome variables

Sedation level; drug complications; pain intensity; Arterial blood pressure; oxygen saturation; heart rate; recovery time

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039326N1**

Registration date: **2018-07-07, 1397/04/16**

Registration timing: **retrospective**

Last update: **2018-07-07, 1397/04/16**

Update count: **0**

##### Registration date

2018-07-07, 1397/04/16

##### 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

2017-03-21, 1396/01/01

##### Expected recruitment end date

2018-03-21, 1397/01/01

##### Actual recruitment start date

2017-03-21, 1396/01/01

##### Actual recruitment end date

2018-03-20, 1396/12/29

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of fentanyl-propofol and pethidine-propofol on the sedation level during cataract surgery by phacoamulsification method

## Public title

A comparative study on the effect of fentanyl-propofol and pethidine-propofol on sedation level during cataract surgery by phacoemulsification method

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients aged 35 to 85 years Patients undergoing cataract surgery by phacoemulsification Patients undergoing local anesthetic sedation in the first and second classes of the American Anesthetic Association

### Exclusion criteria:

History of any allergy to the drug used in the design History of drug addiction, alcohol, benzodiazepine Pregnancy Congestive heart failure History of head trauma Glaucoma Hypotension Evidence of increased intracranial pressure Psychosis Schizophrenia Active upper respiratory tract infection Asthma Chronic respiratory disease

## Age

From **18 years** old to **90 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **80**

Actual sample size reached: **143**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The division of patients into two groups is based on a random number table

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The study is double blinded. Patient and researcher are unaware of patient groups and type of medication. The medications are prepared by an anesthetist who is unaware of the grouping of patients and is worn by an aluminum foil and encoded by an anesthetist. Demographic information; Sedation level. The quality of pain relief and hemodynamic variables and complications are collected by a patient who is not aware of the type of drug and patient grouping.

## 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

Isfahan University of medical sciences, Hezar Jarib Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2018-01-20, 1396/10/30

#### Ethics committee reference number

IR.MUI.REC.1396.3.743

## Health conditions studied

### 1

#### Description of health condition studied

Cataract surgery

#### ICD-10 code

H43.9

#### ICD-10 code description

Unspecified disorder of vitreous body

## Primary outcomes

### 1

#### Description

Sedation level based on Ramsay score

#### Timepoint

Every 5 minutes during surgery

#### Method of measurement

Ramsay score

## Secondary outcomes

### 1

#### Description

arterial pressure

#### Timepoint

Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

#### Method of measurement

pressure gauge

### 2

#### Description

oxygen saturation

### Timepoint

Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

### Method of measurement

Pulse oximeter

## 3

### Description

Heart rate

### Timepoint

Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

### Method of measurement

Pulse oximeter

## 4

### Description

Intensity of pain

### Timepoint

every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

### Method of measurement

Universal Pain assessment tool

## 5

### Description

recovery time

### Timepoint

After completing the intervention until the withdrawal from the recovery

### Method of measurement

Minute Numbers

## Intervention groups

### 1

### Description

Intervention group: first: the combination of fentanyl-propofol. Syringe 1 contains fentanyl 1.5 mcg / kg, which is added by adding 5 cc water. Syringe 3 contains Propofol 0.4 mg / kg at 5 mg / cc and 4 Propofol, 5 mg / cc concentration. In group 1 (PF), the first syringe 1 is injected into the titre. Then, in each case, the syringe number 3 is injected into the titer of the sedation level of 3 or 4 ramsay. At the same time, if necessary, a deep sedation needing a syringe number 4 in 1 cc volumes is recorded as a dental carriage.

### Category

Treatment - Drugs

### 2

### Description

Intervention group: second: the combination of pethidine- propofol. Syringe 2 contains pethidine (0.6 mg / kg) with distilled water at a concentration of 5cc (concentration 10mg / cc). Propofol containing 0.4mg /

kg Propofol (5mg / cc) and Propofol 4 (5mg / cc) will be administered. Group 2 pp) Firstly, the syringe 2 is injected into the header and then injected into the header 3 of the syringe 3 as a 3 or 4 sedation level of ramsay score. In the course of surgery, if you need a deeper sedation than Syringe 4 in 1cc volumes as the dose of salvage and total dose It is recorded.

### 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 Haghjooye Javanmard

#### Street address

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

#### City

Isfahan

#### Province

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#### Postal code

81746-73461

#### Phone

+98 31 3668 0048

#### 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**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Feyz hospital, Modares St

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

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**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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**Email**

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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