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)

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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 phacoamulsification 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 Unoversity of medical sciences, Hezar Jarib Street
City
Isfahan
Province
Isfehan
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
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7346181746
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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.
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81746-73461
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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
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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