Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the sedative effect of Remifentanil and Propofol in Senile Cataract Surgeries under Regional Block

Protocol summary

Summary

The main goal of today's ophtalmosurgery is to control Anxiety, painless procedure and also unwanted movements. The aim of this study was centered on comparison the sedative and hemodynamic effect and side effects of remifentanil and propofol in senile cataract surgeries for optimal drug selection. We performed a prospective, randomized study comparing the efficacy and safety of remifentanil and propofol for conscious sedation during eye cataract surgery. 60 Patients were assigned to receive remifentanil or Propofol in two groups accidentally, each contained 30 subjects. Our Inclusion crietrie was ASA physical status 2,3; Male or female age≥65 ;No Alergic Reaction to Drug ;No Drug abuse; No smoker and our exclusion crieteria was hypoxia; nausea andvomiting. In R (remifentanil) group, patients sedated with bolus doses of 0.5 µg/kg, and maintenance dose of 0.05 µg/kg/min. In P (propofol) group, patients sedated with bolus doses of 0.25 µg/kg and maintenance dose of 25 µg/kg/min. Hemodynamic responses, Oxygen blood level, sedation level and drug side effects were measured at base time and every 10 min till end of operation (OP).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111268201N1**
Registration date: **2012-04-14, 1391/01/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-14, 1391/01/26

Registrant information

Name

Reza Tarjoman Porshokoh

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the sedative effect of Remifentanil and Propofol in Senile Cataract Surgeries under Regional Block

Public title

Sedative effect of Remifentanil in Senile Cataract Surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA physical status 2,3; Male or female age≥65 ; No Allergic Reaction to Drug; No Drug abuse; No smoking. Exclusion criteria: hypoxia; nausea;

vomiting.

Age
From **65 years** old to **85 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Tehran University of Medical Sciences

Street address
Hemmat Pardis, next to Milad Hospital, Hemmat highway

City
Tehran

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
42121

Health conditions studied

1

Description of health condition studied
Cataract

ICD-10 code
H25

ICD-10 code description
Senile incipient cataract

Primary outcomes

1

Description
O2 saturation

Timepoint
During intravenous sedation

Method of measurement
Pulseoximeter

2

Description
Sedation score

Timepoint
Before regional block and every 10 minutes therafter until the end of operation

Method of measurement
MOAA/SS (Modified observer's assessment of alertness/sedation)

3

Description
Blood pressure

Timepoint
During intravenous sedation

Method of measurement
By non-invasive blood pressure measuring

4

Description
Heart rate

Timepoint
During intravenus sedation

Method of measurement
ECG

Secondary outcomes

1

Description
Nausea and vomiting

Timepoint
During intravenous sedation

Method of measurement
Observe

2

Description
Bradycardia

Timepoint
during intravenous sedation

Method of measurement
Electrocardiogram (ECG)

3

Description
Apnea

Timepoint
during intravenous sedation

Method of measurement
Respiratoty Rate

Intervention groups

1

Description
Control group: with bolus doses of 0.25 µg/kg and maintenance dose of 25 µg/kg/min
Category
Treatment - Drugs

2

Description
Intervention group: with bolus doses of 0.5 µg/kg, and maintenance dose of 0.05 µg/kg/min
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotouhi
Street address
Pour-Sina st, 16 Azar ave, Keshavarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran 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
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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