

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 ophthalmosurgery 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 criteria was ASA physical status 2,3; Male or female age ≥ 65 ; No Allergic Reaction to Drug ; No Drug abuse; No smoker and our exclusion criteria was hypoxia; nausea and vomiting. In R (remifentanil) group, patients sedated with bolus doses of 0.5 $\mu\text{g/kg}$, and maintenance dose of 0.05 $\mu\text{g/kg/min}$. In P (propofol) group, patients sedated with bolus doses of 0.25 $\mu\text{g/kg}$ and maintenance dose of 25 $\mu\text{g/kg/min}$. 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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Iran (Islamic Republic of)

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+98 21 8833 3556

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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 thereafter 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 intravenous 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

Respiratory 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

Tehran University of Medical Sciences

Full name of responsible person

Reza Tarjoman Porshokoh

Position

MD

Other areas of specialty/work

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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