Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparison of effects dexmedetomidine and propofol in Vitreoretinal surgery under retrobulbar block and Monitored Anesthesia Care.

Protocol summary

Summary

This study is a double blind clinical trial on 50 patients over 18 years in Hazrat Rasoul Akram hospital with retro bulbar block are undergoing vitrectomy. Inclusion criteria: ASA1-3; age 18 years old and over whom have no contraindications to block retro bulbar. Exclusion criteria: age below 18 years old; patients treated with aspirin or anti-coagulant; uncontrolled hypertension; hyperthyroidism; recurrent cough; drug addiction; hearing impairment; neurological or psychiatric disorder; incomplete block; severe heart disease; a history of sleep apnea and drug allergies. After obtaining informed consent from patients, patients undergoing retro bulbar block placed by an eye surgeon and randomly divided into two groups of 25. One group receives dexmedetomidine(group-d) and other group gets protocol(group-p). For sedation during vitrectomy surgery under local anesthesia was performed. The following assessments will be carried out: 1 - defining sedation levels every 5 minutes during the procedure to achieve an appropriate level of sedation (Ramsay score 3) and BIS 70-80 and then every 15 minutes. 2 - Heart rate, mean arterial pressure, arterial oxygen saturation is recorded every 5 minutes and every 15 minutes similar before ward and 30-15 minutes after procedure. 3 - The recovery of A Ldret score every 5 minutes to discharge the Ldrt score is 10. 4 - Determining the degree of pain using visual.analog.scale-10 cm in 6-1 hours after surgery. 5 - Identify recipients' surgeon satisfaction with 7point likert-like verbal rating scale. For analysis, the data collected will be put in spss software. And the two groups using t test, parameters are compared and is considered to be significant at alpha equal to 5 hundredths. Chi-square test was used to compare groups for variables categorical.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122811620N3**
Registration date: **2013-06-28, 1392/04/07**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-06-28, 1392/04/07

Registrant information

Name
Mohsen Zyaeifard
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Scienses

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of effects dexmedetomidine and propofol in Vitreoretinal surgery under retrobulbar block and

Monitored Anesthesia Care.

Public title
The effect of anesthetic in eye surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria :ASA1-3; age 18 years old and over who have no contraindications to block retro bulbar. Exclusion criteria : age below 18 years old; patients treated with aspirin or anti-coagulant; uncontrolled hypertension; hyperthyroidism; recurrent cough; drug addiction; hearing impairment; neurological or psychiatric disorder; incomplete block; severe heart disease; a history of sleep apnea and drug allergies .
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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
Tehtan
City
Tehran
Postal code
1468944111
Approval date
2013-04-30, 1392/02/10
Ethics committee reference number
17890

Health conditions studied

1

Description of health condition studied
local anesthesia
ICD-10 code
H43.0
ICD-10 code description
Vitreous prolapse

Primary outcomes

1

Description
spo2
Timepoint
before, during and postoperation
Method of measurement
pulse oxymetry

2

Description
sedation degree
Timepoint
before, during and postoperation
Method of measurement
RSS,BIS

3

Description
pain degree
Timepoint
before, during and postoperation
Method of measurement
VSA

4

Description
surgery satisfact,patient satisfaction
Timepoint
before, during and postoperation
Method of measurement
7pointlikert

5

Description
recovery profile
Timepoint
before, during and postoperation
Method of measurement
aldrete.s

6

Description
heart rate
Timepoint
before, during and postoperation
Method of measurement

ECG

7

Description
MPA
Timepoint
before, during and postoperation
Method of measurement
manometer

Secondary outcomes

1

Description
Changes in heart rate and blood pressure
Timepoint
before,during and postoperation
Method of measurement
ECG,Manometer

2

Description
pain
Timepoint
before,during and postoperation
Method of measurement
VAS

3

Description
Hypoxemia
Timepoint
before,during and postoperation
Method of measurement
pulseoximeter

Intervention groups

1

Description
Intervention group or the group D:Dexmedethomedine1 micrograms /kg as a 10 minute intravenous infusion is administered with a pump.Followed by continuous infusion of 0.4 mg per kg of body weight per hour to start,0.1 ppm is added every 5 minutes and patient sedation with BIS and ramssay.sedation.scale previously described for patient assessment becomes With the aim to obtain RSC = 3 and BIS 60-80.
Category
Treatment - Drugs

2

Description
Control group or the P group: Propofol at a dose of 0.3 mg / kg in 10 minutes followed by continuous infusion mg/kg/h0.3 done.Then 0.1 mg every 5 minutes as (little by little) is added. And is evaluated with the aim to obtain RSC = 3 and BIS 60-80.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazratrasul Hospital
Full name of responsible person
Mohsen Ziyaeifard
Street address
Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciiences
Full name of responsible person
Jila chechmi
Street address
Tehran Qods St., Keshavarz Blvd, 4th Floor, Research
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciiences
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
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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