

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparision of topical anesthesia and retrobulbar injection with intra venous sedation on Hemodynamic variability and patients satisfaction in cataract surgery (phaco technique)

Protocol summary

Summary

Patients between 50-90 years old and with ASA class I-III that candidate for Cataract surgery(Phaco technique) in random fixed block include in study and divides two group. The both group receiving IV Sedation at mixture of midazolam 0.5-1 mg and fentayl 0.5-1 mic/kg. First group take retrobulbar block with injection of 2 cc lidocain 2% and Hyaluronidase 1/15000.Second group in Topical anesthesia with Tetracaine 5% , 2-3 drops every 5 minute, maximum 3 times. In during the surgery is continuing monitoring of(Electrocardiography) ECG(level II), BP(blood pressure),O2 saturation and nasal canula with Oxygen, 5 liter/min .Every 5 minutes, HR(Heat rate),SBP(systolic blood pressure),DBP(diastolic blood pressure),MAP(mean artherial pressure),O2 Sat and every 15 minute VAS score and satisfaction score by anesthesiologist assistant is recorded.Time of surgery is 30-43 minutes, if the time of surgery prolonged (more than 60 minutes) or Leads to general anesthesia patients exclude of this study. Hemodynamic variations, analgesia and patient satisfaction in this study, are two objectives .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122815963N1**
Registration date: **2014-02-05, 1392/11/16**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-02-05, 1392/11/16

Registrant information

Name

Soudabeh Haddadi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13332383068

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2014-09-11, 1393/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of topical anesthesia and retrobulbar injection with intra venous sedation on Hemodynamic variability and patients satisfaction in cataract surgery (phaco technique)

Public title

Anesthesia in cataract surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:Patients candidates for elective cataract surgery phaco technique class ASA I, II, III exclusion

criteria: The time of surgery prolonged (more than 60 minutes) or Leads to general anesthesia

Age

From **50 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan university of Medical Sciences

Street address

shahid Beheshti Boulevard

City

rasht

Postal code

4193893345

Approval date

2013-12-07, 1392/09/16

Ethics committee reference number

1920341313

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H18.8

ICD-10 code description

Other specified disorders of cornea

Primary outcomes

1

Description

blood pressure

Timepoint

every 5 minutes during the surgery up to 60 minutes

Method of measurement

Saadat company,digitaly

2

Description

heart rate

Timepoint

every 5 minutes during the surgery up to 60 minutes

Method of measurement

Saadat company,digitaly

Secondary outcomes

1

Description

pain

Timepoint

every 15 minutes up to 60 minutes

Method of measurement

Vas(visual analogue scale)

Intervention groups

1

Description

First group take retrobulbar block with injection of 2 cc lidocain 2% and Hyaluronidaz 1/15000.

Category

Treatment - Drugs

2

Description

Second group in Topical anesthesia with Tetracaine 5% , 2-3 drops every 5 minute, maximum 3 times.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Soudabeh Haddadi

Street address

17 Shahrivar Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of
Medical Sciences

Full name of responsible person

Abdolrasool Sobhani

Street address

Shahid beheshti Highway

City

Rasht

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 of Guilan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Soudabeh Haddadi

Position

Anesthesiologist/Assistant professor

Other areas of specialty/work**Street address**

Amiralmomenin Hospital

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Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Soudabeh Haddadi

Position

Anesthesiologist/Assistant professor

Other areas of specialty/work**Street address**

Amiralmomenin Hospital

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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