

# 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 arthelial 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

##### Email address

so\_haddadi@gums.ac.ir

##### 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

**City**

Rasht

**Postal code**

4139638459

**Phone**

+98 13 1223 8306

**Fax**

+98 13 1222 7409

**Email**

arcguilan1392@gmail.com; so\_haddadi@yahoo.com

**Web page address**

gums.ac.ir

## 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

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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*