

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of the Effect of Intravenous Atropine and Hyoscine on the Frequency of Oculocardiac Reflex in Scleral Buckling Surgery: A double-blinded Randomized Controlled Clinical Trial

#### Protocol summary

##### Study aim

This clinical study was set out to compare the effects of atropine and hyoscine on the frequency of oculocardiac reflex in patients with scleral buckling surgery.

##### Design

Three parallel group randomized trial with three blinded participant, investigator and surgeon for preventive effect of anticholinergics on oculocardiac reflex

##### Settings and conduct

This study is performed in patients with scleral buckling in Khatam Al-Anbia Hospital. After monitoring and intravenous saline injection, induction of anesthesia was performed with 2 mg/kg fentanyl, 0.5 mg/kg atracurium, and 2 mg/kg propofol. After 2 minutes, patients were intubated and after confirmation of the location, the patients were placed under mechanical ventilation with a volume of 8 cc/kg. Respiratory rate was adjusted based on capnography and EtCO<sub>2</sub> was maintained in the range of 35-45 mmHg. Then, according to the protocol, the injection was performed in the control group (distilled water), the atropine group, and the hyoscine group. The solutions were prepared in two ml volume, the patient and the researcher that evaluating the symptoms did not know the injected drugs.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were American Society of Anesthesiologists (ASA) class I and II. Exclusion criteria were: ASA > II, uncontrolled hypertension, coronary artery disease, respiratory disease, addiction, preoperative beta-blocker use, and hypersensitivity to hyoscine and atropine.

##### Intervention groups

After induction, in the control group distilled water, in the atropine group 0.02 mg/kg up to a maximum of 0.5 mg, and in the hyoscine group 0.2 mg/kg was injected

##### Main outcome variables

Patients' vital signs, blood pressure, heart rate, and

capnography were recorded before induction, after induction, and intubation, at the beginning of surgery and every 10 minutes until the end of the operation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120307009229N6**

Registration date: **2022-02-14, 1400/11/25**

Registration timing: **retrospective**

Last update: **2022-02-14, 1400/11/25**

Update count: **0**

##### Registration date

2022-02-14, 1400/11/25

##### Registrant information

##### Name

Mehryar Taghavi Gilani

##### Name of organization / entity

Medical University of Mashhad

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1852 5209

##### Email address

taghavim@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-15, 1398/02/25

##### Expected recruitment end date

2020-03-08, 1398/12/18

##### Actual recruitment start date

2019-05-22, 1398/03/01  
**Actual recruitment end date**  
2020-07-10, 1399/04/20  
**Trial completion date**  
2020-07-10, 1399/04/20

**Scientific title**  
Comparison of the Effect of Intravenous Atropine and Hyoscine on the Frequency of Oculocardiac Reflex in Scleral Buckling Surgery: A double-blinded Randomized Controlled Clinical Trial

**Public title**  
Frequency of Oculocardiac Reflex in scleral buckling

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
American Society of Anesthesiologists (ASA) class I and II  
**Exclusion criteria:**  
ASA > II, uncontrolled hypertension, coronary artery disease, respiratory disease, addiction, preoperative beta-blocker use, hypersensitivity to hyoscine and atropine

**Age**  
From **5 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **75**  
Actual sample size reached: **25**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, a simple randomization method is used and each patient randomly removes a sealed envelope and announces the number inside it to the researcher.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this double-blinded clinical study, the drugs are injected by one person and each drug is prepared in a 2 cc syringe (2ml solution), the researcher who recorded the information and the patient did not know the type of drug prescribed

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
none

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**  
Ethics Committee of Mashhad University of Medical Science

**Street address**  
bahar str

**City**  
mashhad

**Province**  
Razavi Khorasan

**Postal code**  
9184542322

**Approval date**  
2019-05-15, 1398/02/25

**Ethics committee reference number**  
IR.MUMS.MEDICAL.REC.1398.093

## Health conditions studied

### 1

**Description of health condition studied**  
Hypotony of eye and scleral buckling surgery

**ICD-10 code**  
H44.4

**ICD-10 code description**  
Hypotony of eye

## Primary outcomes

### 1

**Description**  
oculocardiac reflex

**Timepoint**  
before induction, after induction, and implantation of the endotracheal tube, at the beginning of surgery and every 10 minutes until the end of the operation

**Method of measurement**  
heart rate changes

## Secondary outcomes

### 1

**Description**  
blood pressure

**Timepoint**  
before induction, after induction, and implantation of the endotracheal tube, at the beginning of surgery and every 10 minutes until the end of the operation

**Method of measurement**  
intraoperative monitoring

## Intervention groups

## 1

### Description

first Intervention group- Hyoscine n-butyl bromide is injected in 20 mg and 2 ml of tolidaru before induction of anesthesia.

### Category

Prevention

## 2

### Description

second Intervention group: Atropine sulfate is injected 0.02 mg/kg up to 0.5 mg in two ml made by Caspian before induction of anesthesia.

### Category

Prevention

## 3

### Description

Control group- Distilled water is injected in two ml before induction of anesthesia

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Khatam Al-Anbia Hospital

#### Full name of responsible person

mehryar taghavi gilani

#### Street address

bahar str

#### City

mashhad

#### Province

Razavi Khorasan

#### Postal code

9184542322

#### Phone

+98 51 3858 3878

#### Email

taghavim@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

mehryar taghavi gilani

#### Street address

bahar str

#### City

mashhad

#### Province

Razavi Khorasan

#### Postal code

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#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mashhad University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

mehryar taghavi gilani

#### Position

associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

#### Street address

bahar str

#### City

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#### Province

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

mehryar taghavi gilani

#### Position

associate professor

#### Latest degree

Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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**Province**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
mehryar taghavi gilani  
**Position**  
associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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**Province**  
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9184532435  
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**Email**  
taghavim@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Demographic characteristics of patients such as age, sex and weight, as well as changes in heart rate and blood pressure during scleral buckling surgery in patients are evaluated and compared with each other.

### When the data will become available and for how long

After 2022 and the publication of articles in scientific journals

### To whom data/document is available

medical students and professors and journal editors

### Under which criteria data/document could be used

except of patient nominal information, patient profiles such as age, sex, weight, and intraoperative hemodynamic changes such as heart rate and blood pressure are available, and individuals are allowed to perform any evaluation and analysis.

### From where data/document is obtainable

To access the study information in the following ways, people can apply and contact to Mehryar Taghavi Gilani tel: 0513858878 taghavim@mums.ac.ir Address: Mashhad Imam Reza Hospital - Anesthesia Ward

### What processes are involved for a request to access data/document

Contact Mehryar Taghavi Gilani for any information about the type and method of study and statistical results, as well as the Data obtained. Phone 0513858878

### Comments