

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 EtCO₂ 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

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taghavim@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

mehryar taghavi gilani

Position

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Person responsible for updating data

Contact

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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