

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of Changes in Heart Rate and Development Cardiac Arrhythmia following Reversal of Muscle Relaxation by Two Combination :Atropine Plus Neosigmine or Glycopyrrolate Plus Neostigmin

Protocol summary

Summary

Objective: In this study two drug combinations; atropine-neostigmine and glycopyrrolate-neostigmine were compared according to their effects on heart rate, blood pressure and arrhythmogenicity. Research Design: Conduction of a randomized, double-blind, clinical trial, method of randomization: simple. Inclusion criteria: patient between 50-70 year old, ASA physical status I, undergoing cataract surgery under general anesthesia with endotracheal tube or laryngeal mask. Exclusion criteria: Patients with electrolyte abnormalities, cardiovascular problems and using the drugs that affect heart rate and also patients with difficult intubation were excluded from the study. Intervention: One hundred elderly patient between 50-70 year old with ASA physical status I, undergoing cataract surgery were randomly allocated in two groups : I) glycopyrrolate-neostigmine (G) and II) Atropine- neostigmine (A)At the end of the operation reversal of the muscle relaxant effects in group I was conducted with combination of atropine-neostigmine and glycopyrrolate-neostigmine in group II. Heart rate, arrhythmia and blood pressure were recorded at 4 time points: 1) before induction of anesthesia .2) after administration of anesthetic drugs and before drug reversal of muscle relaxation 3) Three minutes after reversal of neuromuscular blockade. 4) ten minutes after reversal of neuromuscular blockade.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021019470N16**
Registration date: **2015-04-21, 1394/02/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-21, 1394/02/01

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Changes in Heart Rate and Development Cardiac Arrhythmia following Reversal of Muscle Relaxation by Two Combination :Atropine Plus Neosigmine or Glycopyrrolate Plus Neostigmin

Public title

Comparison of Changes in Heart Rate following Reversal

of Muscle Relaxation by Two Combination :Atropine Plus Neosigmine or Glycopyrrolate Plus Neostigmin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient between 50-70 year old, ASA physical status I, undergoing cataract surgery under general anesthesia with endotracheal tube or laryngeal mask. Exclusion criteria: Patients with electrolyte abnormalities, cardiovascular problems and using the drugs that affect heart rate and also patients with difficult intubation were excluded from the study.

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethic Committee of Shiraz University Of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

ct-88-4553

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H25

ICD-10 code description

Senile Cataract

Primary outcomes

1

Description

Heart Rate

Timepoint

1) before induction of anesthesia .2) after administration of anesthetic drugs and before drug reversal of muscle relaxation 3) Three minutes after reversal of neuromuscular blockade. 4) ten minutes after reversal of neuromuscular blockade.

Method of measurement

EKG

2

Description

Arrhythmia

Timepoint

1) before induction of anesthesia .2) after administration of anesthetic drugs and before drug reversal of muscle relaxation 3) Three minutes after reversal of neuromuscular blockade. 4) ten minutes after reversal of neuromuscular blockade.

Method of measurement

EKG

3

Description

Blood Pressure

Timepoint

1) before induction of anesthesia .2) after administration of anesthetic drugs and before drug reversal of muscle relaxation 3) Three minutes after reversal of neuromuscular blockade. 4) ten minutes after reversal of neuromuscular blockade.

Method of measurement

Measuring the blood pressure

Secondary outcomes

empty

Intervention groups

1

Description

at the end of the operation reversal of the muscle relaxant effects in group I was conducted with combination of atropine-neostigmine

Category

Treatment - Drugs

2

Description

at the end of the operation reversal of the muscle relaxant effects in group II was conducted with combination of glycopyrrolate-neostigmine .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Dr Mehdi Zadmehr

Street address

Namazee Hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

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, Shiraz 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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mehdi Zadmehr

Position

Physician

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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