Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of the injection speed of the combination of neostigmine and atropine on the heart rate of patients under general anesthesia

Protocol summary

Study aim

A lot of surgeries are performed in the world every year, so it is necessary to take the necessary precautions to ensure the safety of the patient as much as possible. A combination of atropine and neostigmine drugs under the name of reverse, which is injected at the end of surgery to neutralize muscle relaxant drugs, can affect cardiovascular stability. The purpose of this study is to find a solution to minimize this effect.

Design

This study is a double-blind clinical trial on 69 hospitalized patients who are candidates for various surgeries, who were randomly divided into three groups based on the speed of reverse injection by giving sheets A, B, and C.

Settings and conduct

A double-blind study involving the researcher and the patient was conducted on inpatients who were candidates for various surgeries in 1400 at Shahid Rahmon Hospital, Yazd, and the information was recorded using a checklist, and the samples were randomly divided into three groups in terms of injection time. They were divided in reverse.

Participants/Inclusion and exclusion criteria

The criteria for inclusion in the study were patients aged 16-50 years, hemoglobin levels higher than 14 g/dL with ASA.PS class one anesthesia. The exclusion criteria were patients with bleeding more than 10% of the blood volume, having cardiac, vascular and respiratory disorders, receiving drugs affecting the heart rate or central nervous system, and patients with a history of substance abuse, drug sensitivity, and egg yolk sensitivity.

Intervention groups

A combination of atropine and neostigmine drugs under the name of reverse, which is equal in each group in terms of dosage (1.5 mg of atropine and 3 mg of neostigmine) and differs only in terms of injection speed (10 seconds, 1 minute, 3 minutes).

Main outcome variables

pulse rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230405057822N1**
Registration date: **2024-01-26, 1402/11/06**
Registration timing: **retrospective**

Last update: **2024-01-26, 1402/11/06**
Update count: **0**

Registration date

2024-01-26, 1402/11/06

Registrant information

Name

Hamid Mirhosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3623 8626

Email address

mirhosseini@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

2021-10-23, 1400/08/01

Actual recruitment end date

2023-04-21, 1402/02/01

Trial completion date

2023-04-21, 1402/02/01

Scientific title

Investigating the effect of the injection speed of the combination of neostigmine and atropine on the heart rate of patients under general anesthesia

Public title

Investigating the effect of the injection speed of the combination of neostigmine and atropine on the heart rate

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Hemoglobin level above 14 g/dL Anesthesia class one ASA.PS

Exclusion criteria:

Patients with bleeding more than 10% blood volume Patients with a history of substance abuse and drug allergy and egg yolk allergy Having cardiac, vascular and respiratory disorders Receiving drugs that affect heart rate or central nervous system

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **69**

Actual sample size reached: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

The studied samples were randomly divided into three groups based on the speed of reverse injection by giving sheets A, B, and C. The injection speed of the first group was 10 seconds, the second group was 1 minute, and the third group was 3 minutes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher was not aware of the speed of the injection of neostigmine and atropine, which was done by the research colleague. Since the patient was not conscious at the time of the injection, he did not know the type of intervention.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Imam Hossein square, at the beginning of the student boulevard, Imam Reza,research educational complex

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۱۸۸۶۳۷

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.SSU.REC.1400.210

Health conditions studied

1

Description of health condition studied

the patients under going general anesthesia

ICD-10 code

Z41.2

ICD-10 code description

Encounter for routine and ritual male circumcision

Primary outcomes

1

Description

pulse rate

Timepoint

10 seconds , 1minute , 3minutes

Method of measurement

monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: reverse injection with a speed of 10 seconds including 3 mg of neostigmine and 1.5 mg of atropine to the first 23 patients.

Category

Treatment - Drugs

2

Description
The second intervention group: reverse injection with a speed of 1 minute including 3 mg of neostigmine and 1.5 mg of atropine to 23 second patients.
Category
Treatment - Drugs

3

Description
The third intervention group: reverse injection with a speed of 3 minutes including 3 mg of neostigmine and 1.5 mg of atropine to 23 third patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Shahid Rahnamoun Hospital
Full name of responsible person
Mohammad Hossein Dehghani
Street address
Farokhi Ave , YAZD
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Hamid Mirhosseini
Position
Assiciate professor
Latest degree
Ph.D.
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Total data
When the data will become available and for how long
3 months after printing the data
To whom data/document is available
Anesthesiologists and experts
Under which criteria data/document could be used
There are no conditions
From where data/document is obtainable
To receive, contact msaleh.forghani@gmail.com
What processes are involved for a request to access data/document
It will be sent after the applicant's identity and documents are authenticated
Comments