Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Atracurium and Cis-Atracurium injection on hemodynamic status and Neutrophil-to-Lymphocyte Ratio (NLR) during anesthesia induction

Protocol summary

Study aim

Comparison of hemodynamic changes and Neutrophil to Lymphocyte Ratio changes caused by Atracurium and Ais-Atracurium injection.

Design

A clinical trial with parallel groups, double-blind, randomized, phase 2 on 80 patients. randomization will be done using a coin toss.

Settings and conduct

This is a randomized double-blind clinical trial that will be conducted on 80 patients in Al-Zahra Hospital, Isfahan. After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients are randomly assigned into groups, the desired intervention is applied in each group, and the blood samples and clinical symptoms of the patient are examined and recorded. The researcher who records the patient's symptoms, laboratory experts, the analyzers, as well as the patients won't know the type of intervention applied in each group and therefore they are all blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 years, class I and II ASA anesthesia, informed consent, and candidate for general anesthesia with Atracurium and Cis-Atracurium Non-Inclusion criteria: history of heart disease and hemodynamic disorders, drug addiction, use of psychedelics, antihistamines, and corticosteroids in the last week, obesity, diabetes, pregnancy, and breastfeeding.

Intervention groups

Intervention group A: In this group of patients, after preparation and connection of monitoring, Sodium Thiopental 5 mg/kg as an anesthetic, Fentanyl 100 micrograms as an analgesic, and also for muscle relaxation 0.5 mg/kg Atracurium within 60 seconds. Intervention group B: In this group of patients, after preparation and connection of monitoring, Sodium Thiopental 5 mg/kg as an anesthetic, Fentanyl 100 micrograms as an analgesic, and also for muscle relaxation 0.15 mg/kg Cis-Atracurium within 60 seconds.

Main outcome variables

Heart Rate, Blood Pressure, Spo2, NLR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N48**
Registration date: **2022-12-11, 1401/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-11, 1401/09/20**
Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Atracurium and Cis-Atracurium injection on hemodynamic status and Neutrophil-to-Lymphocyte Ratio (NLR) during anesthesia induction

Public title

The effect of Atracurium and Cis-Atracurium injection on hemodynamic status and Neutrophil-to-Lymphocyte Ratio (NLR) during anesthesia induction

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18 to 65 years old Anesthesia class I and II according to ASA criteria Candidate for anesthesia with Atracurium and Cis-Atracurium Informed consent to enter the study

Exclusion criteria:

Obesity or BMI (Body Mass Index) of more than 30 History of cardiovascular diseases and hemodynamic disorders or myocardial infarction in the last 6 months Taking psychoactive drugs, antihistamines and corticosteroids in the last week Addiction to opioid and non-opioid drugs Pregnancy and breastfeeding Having diabetes, orthostatic hypotension, bradycardia, hypokalemia, hypothyroidism, depression, long QT syndrome, asthma and allergies

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a simple randomized clinical trial that patients are divided into groups based on flipping a coin; After the first flip of the coin, for the first patient, atracurium is selected for injection in the case of heads, and in the case of tails, cis atracurium is selected. Then, from the second patient onwards, individuals enter the groups one by one until the number reaches 40 people in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind clinical trial so that, before obtaining consent, the patients will be informed of the study but will not be informed about the type of intervention received. Also, the researchers responsible for collecting and analyzing the data won't be informed about the intervention group; therefore, they are all blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib St

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.MUI.MED.REC.1401.230

Health conditions studied

1

Description of health condition studied

Change in hemodynamic status and NLR

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart Rate

Timepoint

before induction of anesthesia and at 3, 10, and 20 minutes after anesthesia

Method of measurement

Electrocardiogram

2

Description
Blood Pressure
Timepoint
before induction of anesthesia and at 3, 10, and 20 minutes after anesthesia
Method of measurement
Sphygmomanometer

3

Description
Oxygen saturation
Timepoint
before induction of anesthesia and at 3, 10, and 20 minutes after anesthesia
Method of measurement
Pulse Oximeter

4

Description
Neutrophil to lymphocyte ratio
Timepoint
before induction of anesthesia and at 3, 10, and 20 minutes after anesthesia
Method of measurement
Cell count of venous blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: In this group, after placing the patients on the surgical bed and connecting the monitoring and establishing two suitable intravenous lines, the first venous blood sample is taken for cell counting and the patient's initial clinical symptoms are measured and recorded. Then, 5 mg/kg Sodium Thiopental made by Elixir Pharmaceutical Company, 100 micrograms of Fentanyl made by Caspin Pharmaceutical Company and 0.5 mg/kg of Atracurium made by Aburihan Pharmaceutical Company are injected to induce anesthesia. Sampling and recording of symptoms are also done in 3, 10 and 20 minutes after anesthesia.
Category
Diagnosis

2

Description
Intervention group B: In this group, after placing the patients on the surgical bed and connecting the monitoring and establishing two suitable intravenous lines, the first venous blood sample is taken for cell counting and the patient's initial clinical symptoms are measured and recorded. Then, 5 mg/kg Sodium Thiopental made by Elixir Pharmaceutical Company, 100 micrograms of Fentanyl made by Caspin Pharmaceutical Company and 0.15 mg/kg of Cis-Atracurium made by Aburihan Pharmaceutical Company are injected to induce anesthesia. Sampling and recording of symptoms are also done in 3, 10 and 20 minutes after anesthesia.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Behzad Nazemroaya
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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
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Behzad Nazem roaya

Position

Professor assistant of Anesthesia and Intensive carentensive care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

Professor assistant of Anesthesia and Intensive carentensive care استادیار بیهوشی و مراقبت های ویژه د

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available