# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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
**Country**
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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**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**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**
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

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## Person responsible for scientific inquiries

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**Latest degree**

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**Other areas of specialty/work**

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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