

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effect of Atracurium and Cisatracurium on post-operative shivering in orthopedic surgery of the lower limbs

#### Protocol summary

##### Study aim

The effect of Atracurium and Cisatracurium on post-operative shivering in orthopedic surgery of the lower limbs

##### Design

The study is done as a double blind randomized clinical trial on patients who candidate for orthopedic surgery. Patients randomly (using computer software) are divided into two groups of 30 cases (A and B).

##### Settings and conduct

The study is done as a double blind randomized clinical trial on patients who are candidate for orthopedic surgery at Shahid Rajaei Hospital in Qazvin. Patient and investigator are not informed of the treatment allocation. Treatment is written on a piece of paper and puts into one envelope and is encrypted confidentially by supervisor.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who completed informed consent form; Patients aged 20 to 60 years. Non-inclusion criteria: Underlying illnesses; Allergy to anesthetic drugs; Abnormal responses to non-depolarized musculoskeletal muscle relaxants.

##### Intervention groups

Group A: administration 0.5 mg / kg Atracurium Group B: administration 0.15-0.2 mg / kg Cisatracurium

##### Main outcome variables

Postoperative Shivering

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170408033291N2**

Registration date: **2019-03-31, 1398/01/11**

Registration timing: **prospective**

Last update: **2019-04-03, 1398/01/14**

Update count: **1**

##### Registration date

2019-03-31, 1398/01/11

##### Registrant information

###### Name

Ali Alizadeh

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3332 0105

###### Email address

a.alizadeh@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-20, 1398/01/31

##### Expected recruitment end date

2020-02-19, 1398/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Atracurium and Cisatracurium on post-operative shivering in orthopedic surgery of the lower limbs

##### Public title

The effect of Atracurium and Cisatracurium on post-operative shivering

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Patients who completed informed consent form Being at the age of 20 to 60 years old Patients in class I and II based on the American Society of Anesthesiologists (ASA) classification

### **Exclusion criteria:**

Underlying illnesses Allergy to anesthetic drugs• Severe allergic to eggs and soy (in relation to propofol)• Abnormal responses to non-depolarized musculoskeletal muscle relaxants such as myasthenia gravis and musculoskeletal disorders, addiction (Narcotics, stimulants and energetic and alcohol) Lack of patient satisfaction to participate in the study Central and peripheral nervous diseases - Multiple trauma

## **Age**

From **20 years** old to **60 years** old

## **Gender**

Both

## **Phase**

3

## **Groups that have been masked**

- Participant
- Investigator

## **Sample size**

Target sample size: **60**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Patients are randomly (using computer software) divided into two groups of 30 cases (A and B). Using a computer, random numbers are generated between 0 and 1. If the generated random number is less than 0.5, the patient is assigned to group A, and if it is greater than 0.5, the patient is assigned to group B.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

In this study patients and investigator are not inform of the treatment groups allocation. Treatment is written on a piece of paper and puts into one envelope and is encrypted confidentially by supervisor.

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

## **Street address**

Shahid Bahonar Blvd., Qazvin

## **City**

Qazvin

## **Province**

Qazvin

## **Postal code**

3419759811

## **Approval date**

2019-03-11, 1397/12/20

## **Ethics committee reference number**

IR.QUMS.REC.1397.405

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Post operative shivering

#### **ICD-10 code**

Y55.2

#### **ICD-10 code description**

Post operative shivering

## **Primary outcomes**

### **1**

#### **Description**

Postoperative Shivering

#### **Timepoint**

After surgery

#### **Method of measurement**

Shivering is evaluated based on the 0-3 scale. Zero (without shivering), grade 1 (mild), grade 2 (moderate), and grade 3 (Severe).

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Group A: Atracurium is injected intravenously with an initial dose of 0.5- 0.6 mg / kg and a concentration of 25 to 50 mg /ml. A preservative dose for muscle relaxation is injected intravenously with dose of 0.1- 0.2 mg/kg upon the onset of muscle relaxation.

Company: Caspian.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group: Group B: Cisatracurium is injected intravenously with an initial dose of 0.15- 0.2 mg /kg body weight and a concentration of 2 to 10 mg /ml. A preservative dose for muscle relaxation is injected

intravenously with dose of 0.03 mg /kg, 40-60 minutes after the initial dose and upon the onset of muscle relaxation. Company: Caspian.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Rajaei Hospital

**Full name of responsible person**

Ahmad Karami

**Street address**

Shahid Rajaei Hospital, Padegan Street, Qazvin

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**Postal code**

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**Phone**

+98 28 3333 5800

**Email**

akkarami1344@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr Amir Peymani

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rajresearch95@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Ahmad Karami

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Ali Alizadeh

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Ahmad Karami

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable