

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)

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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

City

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Qazvin

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3419759811

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+98 28 3333 5800

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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

Street address

Shahid Bahonar Blvd., Qazvin

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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

Street address

Shahid Rajaei Hospital, Padegan Street, Qazvin

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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

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Name of organization / entity

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Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Email

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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