

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of onset, duration and recovery time of neuromuscular blockage of Cis atracurium administration before and after inflation of Tourniquet on upper limb: Randomized clinical trial.

Protocol summary

Study aim

Comparison of onset, duration and recovery time of neuromuscular blockage of Cis atracurium administration, before and after inflation of tourniquet in upper limb

Design

Two arm parallel groups randomized trial with one side blinded caregivers, over 32 patients and random allocation software are used for randomization.

Settings and conduct

In the operation room, after routine monitoring and access to intravenous line, Train of four monitoring (TOF) is placed on both wrist and then induction is done.

Participants/Inclusion and exclusion criteria

Operation is not emergency and needs general anesthesia; Body mass index is between 18 -30 and age is between 20 - 60 years old. Volunteers should not have any history of liver; kidney; severe cardiopulmonary and known neuromuscular disease. They also should not have any vascular disease such as emboly and vascular surgery. Absence of Sickel cell anemia; infection and any fracture or tumor of upper limbs; increased intracranial pressure; acidosis; addiction; any operation of upper limbs; neuromuscular monitoring and use of any drugs that interfere with neuromuscular function are another exclusion criteria.

Intervention groups

Induction starts by injection of 1.5 milligram per kilogram (mg/kg) Lidocaine, Propofol 2 mg/kg and Cis atracurium 0.2 mg/kg in the group A and immediately chronometer start measuring the time. When the Train of four monitoring (TOF), shows complete neuromuscular blockage, the time is recorded and the Tourniquet is inflated up to 100 Mm of mercury (mm hg) above the patient's systolic blood pressure and patient is intubated. Group B receive the same protocol, but only the inflation time of the tourniquet is before administration of Cis

atracurium.

Main outcome variables

Comparison of onset, duration and recovery time of neuromuscular blockage due to administration of Cis atracurium before and after inflation of tourniquet.

General information

Reason for update

contradiction with proposal

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024909N11**

Registration date: **2021-10-09, 1400/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-12, 1401/10/22**

Update count: **1**

Registration date

2021-10-09, 1400/07/17

Registrant information

Name

Faranak Rokhtabnak

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of onset, duration and recovery time of neuromuscular blockage of Cis atracurium administration before and after inflation of Tourniquet on upper limb: Randomized clinical trial.

Public title

Cis atracurium and Tourniquet

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Operation is elective Operation needs general anesthesia
Body mass index is between 18 -30 Age is between 20 - 60 years

Exclusion criteria:

History of liver disease History of kidney disease History of severe cardiopulmonary disease History of known neuromuscular disease such as: Guillain- Barre syndrome, Myasthenia gravis, Organophosphate and Anticholinesterase intoxication, multiple sclerosis disease and history of any musculoskeletal weakness in limbs
Usage of drugs such as: Aminoglycosides, Polymyxin, Lincomycin, Clindamycin, Tetracycline, Calcium, Magnesium, Lithium, Verapamil, Amlodipine, Anti epileptic drugs, Furosemide, Dantrolene, Azathioprine, Steroid and Tamoxifen History of any vascular disease such as: Venous and arterial emboli, any impairment in circulation of limbs, Hemodialysis and history of any surgery on vessels of limbs. Sick cell anemia Acidosis Infection in limbs Fracture in limbs Tumor in limbs Any increase in intracranial pressure Addicted patient Surgery on limbs that were examined If neuromuscular monitoring is necessary during operation

Age

From 20 years old to 65 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, we will use the Balanced Block Randomization method (block size=4). Random allocation software will be used for determining the sequences of blocks. In each block, there are two A for "After" and two B for "Before". For each eligible patient,

the group are determined by randomized selected sequence, and after completing one block (n=4), the next randomized selected sequence will be used to complete next block until all of the eight blocks complete.

Blinding (investigator's opinion)

Single blinded

Blinding description

No information will be provided to clinical caregivers, about which group receive the drug before or after inflation of tourniquet.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

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Iran University of Medical Sciences, Hemmat Highway

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Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.IUMS.FMD.REC.1399.632

Health conditions studied**1****Description of health condition studied**

Cis atracurium

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Onset time of complete neuromuscular blockage.

Timepoint

From administration of Cis atracurium until complete neuromuscular blockage.

Method of measurement

With Chronometer

2

Description

Complete neuromuscular block duration.

Timepoint

The time between complete neuromuscular block until onset of recovery.

Method of measurement

With Chronometer

3

Description

The time of neuromuscular block recovery.

Timepoint

The time between onset of recovery until complete recovery of neuromuscular block.

Method of measurement

With Chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The night before the operation, if there are conditions for inclusion in the study based on inclusion and exclusion criteria, regarding the study and actions taken in this study on the patient and its side effects and benefits are explained to the patient according to the consent form and satisfaction is obtained. Based on the Balanced Block Randomization method, the patient is placed in one of groups A or B. In group A, up on entering the operating room, patients are non-invasively monitored for heart rate, blood pressure, and arterial blood oxygen saturation. Patients are also hydrated by a suitable peripheral vein and pre-oxygenated by a face mask. The tourniquet cuff (RS 3000 made by Ryan, CO. Iran) is closed around the arm which does not have a peripheral vein catheter and also the electrodes which detect train of four (TOF) contraction (TOF Watch SX Organon Ltd Swords, Co. Dublin Ireland) is placed in the wrist of both upper limbs over ulnar nerve and thumb to detect the contractions of adductor pollicis muscle. For sedation, patients received midazolam 0.05 milligram per kilogram of ideal body weight (mg/kg IBW) made by (EXIR, CO. Iran) and fentanyl one microgram per kilogram of ideal body weight ($\mu\text{g/kg}$ IBW) made by (Caspian, CO. Iran) intravenously and after sedation of the patient, train of four (TOF) detector is calibrated. Induction of patients is started by administration of lidocaine 1/5 mg/kg IBW (made by Caspian, CO. Iran) and propofol 2 mg/kg IBW (made by Ferzenius Cabi, CO. Austria) and then Cis atracurium is administered intravenously at a dose of 0/02 mg/kg IBW, (made by Rosa Mod, CO. Iran) and the stopwatch is started immediately. When the TOF count, shows zero number of muscle contractions in one limb, this time indicates that complete block is obtained. At

this time, tourniquet inflates through five seconds up to a pressure of 100 mm Hg over patient's basic blood pressure, and the patient is intubated and the time to reach the block and the duration of the block and the recovery time in both limbs are measured separately. When the sequence of TOF remains zero, this period of time shows complete block. The time between the appearance of the first and second contraction (TOF=1 till 2) is considered as the recovery time. After recording the above parameters, the tourniquet is deflated and the anesthesia is continued with the administration of the appropriate muscle relaxant dose.

Category

Treatment - Devices

2

Description

Control group: In group B, up on entering the operating room, patients are non-invasively monitored for heart rate, blood pressure, and arterial blood oxygen saturation. Patients are also hydrated by a suitable peripheral vein and pre-oxygenated by a face mask. The tourniquet cuff (RS 3000 made by Ryan, CO. Iran) is closed around the arm which does not have a peripheral vein catheter and also the electrodes which detect train of four (TOF) contraction (TOF Watch SX Organon Ltd Swords, Co. Dublin Ireland) is placed in the wrist of both upper limbs over ulnar nerve and thumb to detect the contractions of adductor pollicis muscle. For sedation, patients received midazolam 0.05 milligram per kilogram of ideal body weight (mg/kg IBW) made by (EXIR, CO. Iran) and fentanyl one microgram per kilogram of ideal body weight ($\mu\text{g/kg}$ IBW) made by (Caspian, CO. Iran) intravenously and after sedation of the patient, train of four (TOF) detector is calibrated. Induction of patients is started by administration of lidocaine 1/5 mg/kg IBW (made by Caspian, CO. Iran) and propofol 2 mg/kg IBW (made by Ferzenius Cabi, CO. Austria) and then tourniquet inflates through five seconds up to a pressure of 100 mm Hg over patient's basic blood pressure and then Cis atracurium is administered intravenously at a dose of 0/02 mg/kg IBW, (made by Rosa Mod, CO. Iran) and the stopwatch is started immediately. When the TOF count, shows zero number of muscle contractions in one limb, this time indicates that complete block is obtained. At this time, the patient is intubated and the time to reach the block and the duration of the block and the recovery time in both limbs are measured separately. When the sequence of TOF remains zero, this period of time shows complete block. The time between the appearance of the first and second contraction (TOF=1 till 2) is considered as the recovery time. After recording the above parameters, the tourniquet is deflated and the anesthesia is continued with the administration of the appropriate muscle relaxant dose.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Faranak Rokhtabnak

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Sponsors / Funding sources

1

Sponsor

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Saeed aghakhani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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