Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 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 Sickle 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

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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. Sickle 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
Street address
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 (µg /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 (µg /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

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
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
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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