Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of muscle relaxant dose of cis-atracurium based on body fat mass (FFM), total body weight (TBW) and ideal body weight (IBW) in patients undergoing obesity surgery.

Protocol summary

Study aim

Comparison of muscle relaxant dose of cis-atracurium based on body fat mass, total body weight, and ideal body weight, in patients undergoing obesity surgery.

Design

The present study is a single-blind clinical trial conducted on 60 obese patients who are candidates for bariatric surgery referring to Firoozgar Medical Center (from 96 to 98). Randomization is done using identical envelopes. These envelopes are provided to patients, based on the envelopes they have selected in one of three study groups (FFM-TBW - IBW), which according to inclusion and exclusion criteria, eventually 60 The plan is selected.

Settings and conduct

This study is performed on patients undergoing obesity surgery referred to Firoozgar Hospital during the years 1396-1989. The amount of muscle relaxant required in these three groups with TOF monitoring during surgery, need to be repeated repeatedly.The TOF is monitored during surgery. The comparison of the duration of the patient's muscle relaxation after cis-atracurium infusion was discontinued in the three study groups.Time to reach TOF 4, comparison of amount of rivers consumed in the three study groups, comparison of time interval between rivers administration to appropriate conditions for acquisition in three groups, length of time to reach TOF 4 after rivers injection and surgeon satisfaction from field Diaphragm operation and relaxation are measured and recorded.

Participants/Inclusion and exclusion criteria

Ages 18 to 60 ، ،BMI greater than ²35 kg / .Pregnancy ,Neuromuscular Disease,Treatment with Well-known Interventions in Muscle Neurotransmission، Psychological Disorder,Allergy to Cis-atracurium,

Intervention groups

Our intervention is cisatracurium, which is injected according to study objectives into three groups: body fat mass, total body weight and ideal body weight .

Main outcome variables

Duration of anaesthesia, ,Time of TOF, quality of intubation,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024909N9**
Registration date: **2020-03-11, 1398/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**
Update count: **0**

Registration date

2020-03-11, 1398/12/21

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

2020-01-29, 1398/11/09

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of muscle relaxant dose of cis-atracurium based on body fat mass (FFM), total body weight (TBW) and ideal body weight (IBW) in patients undergoing obesity surgery.

Public title
Comparison of muscle relaxant dose of cis-atracurium based on body fat mass (FFM), total body weight (TBW) and ideal body weight (IBW) in patients undergoing obesity surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ages 18 to 60 Patients with physical level below 3 according to the American Society of Anesthesiologists classification BMI greater than ²35 kg / m Normal kidney and liver function confirmed by routine screening tests
Exclusion criteria:
Pregnancy , Neuromuscular Disease Treatment with Well-known Interventions in Muscle Neurotransmission Psychological Disorder Allergy to Cis-atracurium Criteria for Difficult Intubation
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done using identical envelopes, each envelope containing the name of one of the groups under study. These envelopes are available to patients who are candidates for bariatric surgery. They fall into one of three study groups (FFM - TBW - IBW) based on their envelope. According to the inclusion and exclusion criteria, 60 patients were finally selected for the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are divided into study groups using the same prepared envelopes and none of the patients are aware of the assigned group.
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
No. 14 , Dejamjo Ave., Kamranieh Town
City
Tehran
Province
Tehran
Postal code
553406080050
Approval date
2020-01-21, 1398/11/01
Ethics committee reference number
IR.IUMS.FMD.REC.1398.465

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Duration of muscle relaxation
Timepoint
During surgery
Method of measurement
Minutes

2

Description
Dose of Cisatracurium
Timepoint
During surgery
Method of measurement
Mg, syringe

Secondary outcomes

1

Description
Need for antagonism
Timepoint
During surgery and after surgery
Method of measurement
Mg, syringe

Intervention groups

1

Description
Intervention group1:In the first group, the dose of cis atracurium was injected based on body fat mass (FFM) and changed during the dose of the drug based on the patient's hemodynamic status. It is categorized as non-dollarized. It is used in the anesthesia process for intubation and relaxation of skeletal muscle to facilitate surgery as well as mechanical ventilation of the patient. Cis atracurium is categorized by time of action except for moderate to effective medications. Ampoule concentration is 2 mg / ml, 2.5 ml and manufactured by the Daruyab company.
Category
Treatment - Drugs

2

Description
Intervention group2: In the second group, the dose of cisatracurium is injected based on total body weight (TBW) and changes in the dose of the drug are based on the patient's hemodynamic status during surgery.It is categorized as non-dollarized. It is used in the anesthesia process for intubation and relaxation of skeletal muscle to facilitate surgery as well as mechanical ventilation of the patient. Cis atracurium is categorized by time of action except for moderate to effective medications. Ampoule concentration is 2 mg / ml, 2.5 ml and manufactured by the Daruyab company.
Category
Treatment - Drugs

3

Description
Intervention group: In the third group, the dose of cisatracurium is injected based on ideal body weight (IBW) and changes in the dose of the drug are based on the patient's hemodynamic status during surgery.It is categorized as non-dollarized. It is used in the anesthesia process for intubation and relaxation of skeletal muscle to facilitate surgery as well as mechanical ventilation of the patient. Cis atracurium is categorized by time of action except for moderate to effective medications. Ampoule concentration is 2 mg / ml, 2.5 ml and manufactured by the Daruyab company.
Category
Treatment - Drugs

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
Iran University of Medical Sciences
Full name of responsible person
Dr. Sied Abass Motavaliian
Street address
Floor 5- Iran University of Medical Sciences-next to Milad Tower- Hemat High Way
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Postal code
1449614535
Phone
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Email
research-m@iums.ac.ir
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

Faranak Rokhtabnak

Position

Associate Professor

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

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