Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of two methods of calculating the dose of propofol for induction of general anesthesia according to either Ideal Body Weight(IBW) or Fat Free Mass(FFM), in morbid obese patient: parallel double - blinded clinical trial

Protocol summary

Study aim

Selecting the appropriate drug dose calculation method to induce anesthesia with propofol based on IBW or FFM , which will ultimately prevent drug overdose and reduce drug side effects.

Design

Clinical trial, randomized, double_ blinded, parallel group design of 40 patients.

Settings and conduct

40 patients with obesity and candidates for morbid obesity surgery are selected. Patients are divided into two groups based on the dose of propofol received to induce anesthesia. The patient is asked to hold a 20 cc syringe of normal saline. Propofol is injected in 15 seconds at a dose of 2 mg / kg based on the weight of the study group through a Cath-TEC with 10 cc of normal saline. Decreased alertness is determined by dropping the syringe. The patient is then asked to open his eyes and an eyelid test is performed. Indicators such as depth of anesthesia, heart rate and blood pressure are then measured. Finally, by comparing the results, we will reach the appropriate dose to induce anesthesia in patients with morbid obesity. This study is performed in Firoozgar Hospital

Participants/Inclusion and exclusion criteria

40 patients with obesity over body mass over 35, age 18-59 years, ASA two and three who are selected as candidates for morbid obesity surgery. Patients are divided into two groups based on the dose of propofol received to induce anesthesia, IBW or FFM. Patients with difficult airway, need for awake intubation, severe systemic disease, hepatic or renal impairment, drug allergies, behavioral disorders, or psychiatric medications were not included in the study.

Intervention groups

First group: Patients by calculating weight based on FFM

Second group: Patients by calculating weight based on IBW In both groups, propofol is injected in 15 seconds at a dose of 2 mg / kg based on the calculated weight.

Main outcome variables

Blood pressure, heart rate, decreased consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049135N1**

Registration date: **2021-02-06, 1399/11/18**

Registration timing: **prospective**

Last update: **2021-02-06, 1399/11/18**

Update count: **0**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

Farnoosh Tavakoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8824 9533

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tavakoli_f78@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date
2021-06-20, 1400/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two methods of calculating the dose of propofol for induction of general anesthesia according to either Ideal Body Weight(IBW) or Fat Free Mass(FFM), in morbid obese patient: parallel double - blinded clinical trial

Public title
Comparison of two methods of dose calculating of propofol for induction of general anesthesia according to either Ideal Body Weight(IBW) or Fat Free Mass(FFM), in morbid obese patient: parallel double - blinded clinical trial
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Obesity BMI more than 35 Age 18-59 years ASA ll and lll Undergoing for bariatric surgery
Exclusion criteria:
Difficult airway The need for awake intubation Severe systemic diseases Impaired renal and hepatic function History of allergies to the drugs studied Behavioral disorders and the use of psychiatric drugs
Age
From **18 years** old to **59 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups.To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC
Blinding (investigator's opinion)
Double blinded
Blinding description
The anesthesiologist who is going to administer the drug is aware of the study group, while data recording is performed by another person who is not aware of the administered dose. This is a randomized double-blind study in which the patient and the person who recording and evaluating the data is not aware of the dose of the drug administered.
Placebo
Not used
Assignment
Parallel
Other design features
40 morbid obese patients with BMI more than 35, aged 18-59 years, ASA ll and lll undergoing bariatric surgery, based on the dose of propofol received to induce general anesthesia, into two groups: Fat Free Mass (FFM) and Ideal Body Weight (IBW) are divided.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research School of Medicine - Iran University of Medical Sciences
Street address
No. 6, 35th St., Gisha Ave..
City
Tehran
Province
Tehran
Postal code
1447935167
Approval date
2020-10-17, 1399/07/26
Ethics committee reference number
IR.IUMS.FMD.REC.1399.431

Health conditions studied

1

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

Primary outcomes

1

Description
Onset time of the dose of propofol (electroencephalographic depression) according to the study group which is determined by a decrease in bispectral index to less than 60
Timepoint
During induction of general anesthesia
Method of measurement
evaluated by bispectral index recording

Secondary outcomes

1

Description
Evaluation of the extent of decrease in mean arterial pressure
Timepoint
During induction of anesthesia and every 3 minutes
Method of measurement
Through noninvasive blood pressure monitoring

2

Description
Measure the maximum depth of anesthesia
Timepoint
During induction of anesthesia and every 3 minutes
Method of measurement
Bispectral index Monitoring

3

Description
Evaluation of the extent of heat rate decrease during induction of anesthesia
Timepoint
Continuous monitoring
Method of measurement
Electrocardiography

Intervention groups

1

Description
Intervention group1: Propofol 1% (B.Braun Melsungen AG,34209 Melsungen, Germany) administration with the dose of 2 milligram per kilogram according to ideal body weight(IBW).
Category
Other

2

Description
Intervention group2: Propofol 1% (B.Braun Melsungen AG,34209 Melsungen, Germany) administration with the dose of 2 milligram per kilogram according to body fat free mass(FFM).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Farhad Zamani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Jalil koohpaiehzadeh
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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
Soudabeh Djalali Motlagh
Position
Assisstant Professor
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Participants' personal data is shared after identifying individuals and the main outcome of the study.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Only researchers working in academic and scientific institutions
Under which criteria data/document could be used
Use the appropriate dose of medication to induce general anesthesia and prevent drug side effects
From where data/document is obtainable
E-mail
What processes are involved for a request to access data/document
Send email
Comments