

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Investigating the appropriate dose of sodium thiopental for induction of anesthesia in patients with BMI greater than 25 who undergo surgery with tracheal intubation

Protocol summary

Study aim

Investigating the appropriate dose of sodium thiopental for induction of anesthesia in patients with BMI greater than 25 with BIS monitoring who undergo general surgery

Design

Clinical trial, with three parallel groups, single-blinded, randomized and including 90 patients. The rand function of Excel software is used for randomization.

Settings and conduct

To induce general anesthesia in patients, three different formulas are used based on weight, and the depth of anesthesia and vital signs are measured. The patients are all candidates for elective surgery, and the study is performed in the operating room of Mehdi Clinic, Imam Khomeini Hospital. Patients do not know which group they are in.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Age 20 to 60 years 2- ASA CLASS 1&2 3- ASA CLASS 3 if it is due to BMI more than 40 4- Obtaining informed consent to participate in the project 5- BMI>25

Intervention groups

Patients were divided into three groups based on the method of calculating the initial dose of sodium thiopental. Three groups include: 1- Initial dose based on total body weight 2- Initial dose based on ideal body weight with the following calculation formula: (Male: Ideal Body Weight (kg) = 50 kg + 2.3 kg per inch (2.54 cm) over 5 feet (152 cm). Female: Ideal Body Weight (kg) = 45.5 kg + 2.3 kg per inch over 5 feet) 3- Initial dose based on adjusted body mass with the following calculation formula: Adjusted body mass = Ideal body weight + 0.4 (Total body mass - ideal body weight

Main outcome variables

Depth of anesthesia; heart rate; mean arterial pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230825059254N1**

Registration date: **2023-09-30, 1402/07/08**

Registration timing: **prospective**

Last update: **2023-09-30, 1402/07/08**

Update count: **0**

Registration date

2023-09-30, 1402/07/08

Registrant information

Name

Amirhossein Farhadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3823 1782

Email address

am.farhady@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the appropriate dose of sodium thiopental for induction of anesthesia in patients with BMI greater than 25 who undergo surgery with tracheal intubation

Public title

Investigating the appropriate dose of sodium thiopental for induction of anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA Class I and II ASA Class III if it is due to BMI more than 40 BMI more than 25 obtaining informed consent

Exclusion criteria:

Patients with age less than 20 years or more than 60 years Discontentment with the project ASA Class IV and V Patients with unstable hemodynamics, hemorrhagic shock and heart failure Recent abuse of morphine or any other drugs Patients with porphyria, asthma, uncontrolled hypertension and hypothyroidism Patients with lowering of consciousness Patients with drug allergies Patients requiring second laryngoscopy or failed intubation

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the existence of three groups of thirty members in the study, 6 blocks of three were created: 1. ABC 2. ACB 3. BAC 4. BCA 5. CAB 6. CBA A: Sodium thiopental is injected to the patient based on total body weight. B: Based on ideal body weight, sodium thiopental is injected to the patient. C: Based on adjusted body mass, sodium thiopental is injected to the patient. Using Excel software, a random number between 0 and 9 is created. The block corresponding to each number indicates on what basis each patient receives sodium thiopental. To reach a sample size of 90 (30 people in each group), this work is repeated 30 times. Random numbers zero, 7, 8 and 9 are ignored.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients were unaware of which study group they were in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.174

Health conditions studied

1

Description of health condition studied

Appropriate dose of sodium thiopental for induction of anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bispectral Index

Timepoint

Before induction of anesthesia, after injection of sodium thiopental, three minutes after induction of anesthesia

Method of measurement

BIS monitoring

Secondary outcomes

1

Description

Heart Rate

Timepoint

Before induction of anesthesia, after injection of sodium thiopental, three minutes after induction of anesthesia

Method of measurement

Pulse oximetry

2

Description

Mean Arterial pressure

Timepoint

Before induction of anesthesia, after injection of sodium thiopental, three minutes after induction of anesthesia

Method of measurement

NIBP monitoring

Intervention groups

1

Description

Intervention group: In the first intervention group, sodium thiopental was calculated and injected based on total body weight to induce anesthesia.

Category

Other

2

Description

Intervention group: In the second intervention group, sodium thiopental was calculated and injected based on ideal body weight to induce anesthesia.

Category

Other

3

Description

Intervention group: In the third intervention group, sodium thiopental was calculated and injected based on adjusted body mass to induce anesthesia.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex

Full name of responsible person

Amirhossein Farhadi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Amirhossein Farhadi

Position

Anesthesiology assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Amirhossein Farhadi

Position

Anesthesiology assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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