

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of the effect of fentanyl and morphine on hemodynamic changes during abdominal surgery

Protocol summary

Study aim

Determination of the effect of fentanyl and morphine on hemodynamic changes during abdominal surgery

Design

The clinical trial has a control group (receiving fentanyl) and a control group (receiving morphine) with parallel, double-blind, randomized phase 3 groups on 36 patients. Excel software rand function was used for randomization.

Settings and conduct

In this study, which will be conducted as a clinical trial, 36 patients who are candidates for abdominal surgery in patients referred to Amir Al-Momenin Hospital in Tehran during the years 1399-1400 are included in the study. Demographic information of patients, including demographic characteristics, clinical information and indicators Patients will be observed and collected in the laboratory. Hops specimen is performed by establishing a suitable intravenous route and complete monitoring by injecting 2 mg midazolam 3 cc fentanyl and thiopental and atracurium induction of anesthesia. Gram is injected per hour and hemodynamic changes are measured and data analysis is performed with SPSS software version 25.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Complete information of the participants 2. Age 18 years and older 3. Candidate for abdominal surgery Exclusion criteria: 1. Psychiatrists 2. Drug addiction 3. Cardiovascular diseases and blood pressure

Intervention groups

The clinical trial has a control group (receiving fentanyl) and a control group (receiving morphine). Determination of the effect of fentanyl and morphine on hemodynamic changes during abdominal surgery in Amir Al-Momenin Hospital, Tehran Community Verified icon

Main outcome variables

systolic blood pressure; diastolic blood pressure; heart rate; respiratory rate;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210928052617N1**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

mahtab barkhabeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4426 4451

Email address

mahtabbarkhabeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of fentanyl and morphine on hemodynamic changes during abdominal surgery

Public title
Evaluation of the effect of fentanyl and morphine on hemodynamic changes during abdominal surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
complete identity profile age 18 years and higher candidates for abdominal surgery
Exclusion criteria:
psychiatric drug users opioid drug addict cardio vascular disease, hypertension

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
36 patients who are candidates for abdominal surgery referred to Amir Al-Momenin Hospital in Tehran during the years 1399-1400 are available to study Each person is randomly assigned to one of two groups The randomization method is simple and individual randomization unit The tool used in randomization is Excel software

Blinding (investigator's opinion)
Double blinded

Blinding description
Both groups participating in the clinical trial (morphine group and fentanyl group) enter the trial randomly. The drugs are taken in two syringes and equal volumes, and in the form of a score of 1, 2, or a and b, which the collector does not know, as well as the surgeon and the patient, so he is both blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences
Street address
No4, 6 west boostan alley, 35 lale Ave, Marzadaran Blvd, Tehran town
City
Tehran
Province
Tehran
Postal code
1461776195
Approval date
2021-04-27, 1400/02/07
Ethics committee reference number
IR.IAU.TMU.REC.1400.002

Health conditions studied

1

Description of health condition studied
pulse rate changes

ICD-10 code
R00

ICD-10 code description
Abnormalities of heart beat

2

Description of health condition studied
respiratory rate changes

ICD-10 code
R09

ICD-10 code description
Other symptoms and signs involving the circulatory and respiratory system

3

Description of health condition studied
blood pressure changes

ICD-10 code
R03

ICD-10 code description
Abnormal blood-pressure reading, without diagnosis

Primary outcomes

1

Description
blood pressure changes

Timepoint
Evaluation of blood pressure changes in the first 10 minutes after induction of anesthesia and then the average changes per hour of operation and recoveryCommunity Verified icon

Method of measurement
vital sign monitoring

2

Description

pulse rate

Timepoint

Evaluation of pulse rate changes in the first 10 minutes after induction of anesthesia and then the average changes per hour of operation and recoveryCommunity Verified icon

Method of measurement

vital sign monitoring

3

Description

respiratory rate

Timepoint

Evaluation of respiratory rate changes in the first 10 minutes after induction of anesthesia and then the average changes per hour of operation and recoveryCommunity Verified icon

Method of measurement

vital sign monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After establishing a proper venous route and complete monitoring, anesthesia is induced by injection of 2 mimidazolam, 3 cc of fentanyl, thiopental and atracurium, and then 1 cc of fentanyl is injected every hour and hemodynamic changes are measured.Community Verified icon

Category

Treatment - Drugs

2

Description

Control group: After establishing a proper venous route and complete monitoring, anesthesia is induced by injection of 2 mimidazolam, 3 cc of fentanyl, thiopental and atracurium, and then 2 mg of morphine is injected every hour and hemodynamic changes are measured.Community Verified icon

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-momenin Hospital

Full name of responsible person

Mahtab Barkhabeh

Street address

Amiral momenin hospital,Shimohammadi Ave,Nazi abad st,Tehran town

City

Tehran

Province

Tehran

Postal code

1811694784

Phone

+98 21 5534 6552

Email

amhos@iautmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shabnam Movaseghi

Street address

Islamic azad university of tehran,Daneshgar Ave, zargande ,Tehran Town

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

mahtabbarkhabeh@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University of Tehran, Medical branch

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahtab Barkhabeh

Position

Medical student(intern)

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

Street address

No4, 6 west boostan,35 laleh Ave,Marzadaran
blvd,Tehran town

City

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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