

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effect of fentanyl and remifentanyl alone versus the effect of adding propofol to fentanyl and remifentanyl on postoperative pain intensity in patients who are candidates for cosmetic abdominal surgery

Protocol summary

Study aim

Comparison of the effect of fentanyl and remifentanyl alone versus the effect of adding propofol to fentanyl and remifentanyl on postoperative pain intensity in patients who are candidates for cosmetic abdominal surgery

Design

Clinical trial with two intervention groups, with parallel groups, phase 3 on 36 patients.

Settings and conduct

Amir al-Momenin Hospital, In recovery and at 6, 12, and 24 hours after the operation, the amount and intensity of the pain after the operation is measured and compared by the student based on the VAS pattern, and it is done by the researcher or analyst in the analysis stage. And in those with moderate and severe pain, pethidine is injected in the amount of 10mg to 30mg. Finally, the information is entered into the statistical software spss version 26 and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: electiveness of action; no use of drugs and alcohol; sign the informed consent form to enter the study. Exclusion criteria: the duration of the operation is more than 4 hours; abnormal intraoperative bleeding.

Intervention groups

After general anesthesia with midazolam, fentanyl, sodium thiopental, and atracurium, during anesthesia and surgery in the first group: 1 cc of fentanyl per hour and 2 mg of remifentanyl infusion. In the second group: 1 cc of fentanyl per hour and remifentanyl at the rate of 2 mg are given and the same group receives propofol at the rate of 30 cc per hour.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241027063515N1**

Registration date: **2024-12-08, 1403/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2024-12-08, 1403/09/18**

Update count: **0**

Registration date

2024-12-08, 1403/09/18

Registrant information

Name

Ghazale Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3657 4633

Email address

ailarghasemi98@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of fentanyl and remifentanyl alone versus the effect of adding propofol to fentanyl and remifentanyl on postoperative pain intensity in patients who are candidates for cosmetic abdominal surgery

Public title

Comparison of the effect of fentanyl and remifentanyl alone versus the effect of adding propofol to fentanyl and remifentanyl on postoperative pain intensity in patients who are candidates for cosmetic abdominal surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Effectiveness of action No use of drugs and alcohol Sign the informed consent form to enter the study

Exclusion criteria:

The duration of the operation is more than 4 hours Abnormal intraoperative bleeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Islamic Azad University of Medical Sciences

Street address

Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St, Ayane Blvd, Amir Pabarja St, Golhak Road, Dr. Shariati St, Tehran

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2024-06-29, 1403/04/09

Ethics committee reference number

IR.IAU.TMU.REC.1403.166

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Pain after surgery

Timepoint

in recovery and at 6, 12 and 24 hours after the operation

Method of measurement

VAS Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group: 1 cc of fentanyl per hour and 2 mg of remifentanyl infusion.

Category

Prevention

2

Description

The second group: 1 cc of fentanyl per hour and remifentanyl at the rate of 2 mg are given and the same group receives propofol at the rate of 30 cc per hour.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirul Mominin Hospital, Tehran

Full name of responsible person

Ghazaleh Ghasemi
Street address
In front of Sardar Jangal Park, Hospital, Shahid
Shirmohammadi St., Naziabad
City
Tehran
Province
Tehran
Postal code
1811694784
Phone
+98 21 5534 6550
Email
ailarghasemi98@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoud Parsa Nia

Street address

Headquarters Building of Tehran Islamic Azad
University of Medical Sciences, Corner of Gol Yakh St,
Ayane Blvd, Amir Pabarja St, Golhak Road, Dr.
Shariati St, Tehran

City

Tehran

Province

Tehran

Postal code

1949635881

Phone

+98 21 2660 2642

Email

mparsania@iautmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University
Full name of responsible person

Ghazaleh Ghasemi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Headquarters Building of Tehran Islamic Azad
University of Medical Sciences, Corner of Gol Yakh St,
Ayane Blvd, Amir Pabarja St, Golhak Road, Dr.
Shariati St, Tehran

City

Tehran

Province

Tehran

Postal code

1949635881

Phone

+98 21 2660 2642

Email

ailarghasemi98@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ghazaleh Ghasemi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Headquarters Building of Tehran Islamic Azad
University of Medical Sciences, Corner of Gol Yakh St,
Ayane Blvd, Amir Pabarja St, Golhak Road, Dr.
Shariati St, Tehran

City

Tehran

Province

Tehran

Postal code

1949635881

Phone

+98 21 2660 2642

Email

ailarghasemi98@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ghazaleh Ghasemi

ailarghasemi98@yahoo.com

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Headquarters Building of Tehran Islamic Azad
University of Medical Sciences, Corner of Gol Yakh St,
Ayane Blvd, Amir Pabarja St, Golhak Road, Dr.
Shariati St, Tehran

City

Tehran

Province

Tehran

Postal code

1949635881

Phone

+98 21 2660 2642

Email

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 further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available