

# 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

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**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

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**Province**

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**Postal code**

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**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

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Latest degree**

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**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