# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## Investigating the effect of adding pethidine to Marcaine on the Score of postoperative pain with spinal anesthesia in candidates for abdominal surgery

## Protocol summary

**Study aim**

General purpose: Determining the effect of adding pethidine to marcaine on postoperative pain score with spinal anesthesia in patients who are candidates for abdominal surgery referred to Amirul Mominin Hospital in Tehran city in 1402-1403

**Design**

A clinical trial with a control group, with parallel groups, single-blind, randomized, phase 3 on 58 patients. online random number table was used for randomization.

**Settings and conduct**

This clinical trial study is conducted in Tehran and Amirul Mominin Hospital in 1403-1402. 29 samples in each group and a total of 58 samples are included in the study. Patients are divided into intervention and control groups by online random number table. Demographic information of patients is entered in the data collection form. The study is a single-blinded study in which the participants are unaware of the allocation of the study groups so that the desired drugs are drawn and combined in the spinal syringe before the surgery so that neither the patient nor the surgeon knows the drug being used in spinal and all patients in 2 groups are given spinal anesthesia with a 26 gauge needle in the same conditions. In the control group only marcaine is injected in the amount of 3cc and in the intervention group pethidine is added to marcaine in the amount of 25mg, then in recovery and at 6, 12, and 24 hours after the operation, the pain score after the operation is measured based on the VAS pattern.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: 1. Electiveness of operation 2. Age 18-65 years Exclusion criteria: 1. Anesthesia class above 3 2. History of allergy to pethidine and marcaine drugs

**Intervention groups**

In the control group, only 3cc of marcaine will be injected, and in the intervention group, 25mg pethidine will be added to the marcaine.

**Main outcome variables**

Pain score in recovery and 6, 12, 24 hours in two intervention and control groups

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20231204060259N1**
Registration date: **2024-01-01, 1402/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-01, 1402/10/11**
Update count: **0**

**Registration date**

2024-01-01, 1402/10/11

**Registrant information**

**Name**

Sina Moghadasian Naeini

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2611 4678

**Email address**

sinamoghadasian@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-12-03, 1402/09/12

**Expected recruitment end date**

2024-12-02, 1403/09/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of adding pethidine to Marcaine on the Score of postoperative pain with spinal anesthesia in candidates for abdominal surgery

**Public title**

Investigating the effect of adding pethidine to Marcaine on postoperative pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Electiveness of surgery ASA1,2 Age 18-65 years Signing a personal consent form to enter the study No use of drugs and alcohol

**Exclusion criteria:**

Emergency patients Anesthesia class above 3 History of allergy to marcaine and pethidine drugs

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **58**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done in the simple method (randomization based on a single sequence of random assignments). The randomization unit is individual. The randomization tool is an online random number table, so that from right to left, even numbers are considered for the intervention group and odd numbers are considered for the control group. To perform allocation concealment, each of the generated random sequences is written on a card, and the cards are placed in opaque, sealed and completely identical envelopes in order. To maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box respectively. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. Patients are divided into two groups, 29 samples in each group and a total of 58 samples are included in the study.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The drugs (which in the intervention group include marcaine and pethidine and in the control group only include marcaine) are drawn and combined in the spinal syringe before the surgery so that neither the patient nor the surgeon knows about the drug used in the spinal. Then, after the patients enter the operating room, all the patients in the same conditions in 2 groups get spinal anesthesia with a 26 needle.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

The research ethics committee of medical school - Islamic Azad University of Medical Sciences, Tehra

**Street address**

13th floor, Block A, Treatment and Medical Education, Central Headquarters of the Ministry of Health, Simai Iran Street, between South Flamek and Zarafshan, Quds town (West)

**City**

Tehran

**Province**

Tehran

**Postal code**

1916893813

**Approval date**

2023-11-27, 1402/09/06

**Ethics committee reference number**

IR.IAU.TMU.REC.1402.216

## Health conditions studied

### 1

**Description of health condition studied**

pain score

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Postoperative pain score

**Timepoint**

Measurement of pain score in recovery, 6, 12, 24 hours in two intervention and control groups

**Method of measurement**

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: 25 mg of pethidine (Aburaihan pharmaceutical Co) is added to marcaine (Pharmed company) in the amount of 3 cc.
**Category**
Rehabilitation

### 2

**Description**
Control group: Only Marcaine (Pharmed company) is injected in the amount of 3cc.
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Amiral mominin hospital
**Full name of responsible person**
Dr. Abasat Mirzaei
**Street address**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Dr. Majid Meshkini
**Street address**
Central Organization of Islamic Azad University, Shohdai Hesarek Blvd., University Square, Shahid Sattari Highway
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**Web page address**
https://rti.iau.ir/fa/
**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**
Sina Moghadasian Naeini
**Position**
Medical Intern
**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner
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## Person responsible for scientific

## inquiries

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## Person responsible for updating data

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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 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