Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Amiral Mominin Hospital, Shirmohammadi St., Naziabad
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1811694784
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Web page address
https://tms.iau.ir/amhos/fa/

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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Province
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Postal code
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Phone
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Email
mtfn@iau.ac.ir
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
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Other areas of specialty/work
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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