Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of use of preoperative mexiletine tablets and placebo on reducing postoperative pain in patients undergoing abdominal surgery

Protocol summary

Study aim

Determining and comparing the effect of using mexiltine tablets before surgery with placebo on reducing postoperative pain in patients who are candidates for abdominal surgery in Tehran Azad University hospitals

Design

The sample size is 37 people and there are 17 people in each group. It is a phase 2 study. According to the table of random numbers, the patients are divided into two groups A (recipients of 600 mg mexiltine tablets) and B (recipients of vitamin C tablets). In the first hour after the operation and in the 6th, 12th, and 24th hours after the operation, the pain level of the patients is checked based on the Visual Analog Scale (VAS) model and recorded in the questionnaire, and in the case of VAS>5, pethidine 30-50mg is given to the patients. It is injected intravenously and at the end of the first day, the amount of narcotic used is recorded in the questionnaire by a trained nurse.

Settings and conduct

The drugs were divided by the head of the surgery department in the form of A/B (A receiving mexilten tablets and B receiving vitamin C tablets). The doctor and the patient were not aware of which group the patient was in. Medicines were administered to the patients upon entering the operating room and in the recovery room

Participants/Inclusion and exclusion criteria

Entry conditions: Being 15-75 years old Informed and written consent Non-use of drugs and alcohol Elective surgery Conditions of non-entry: Decreased level of consciousness Hemodynamic disorder Abnormal intraoperative bleeding Time of operation more than 4 hours

Intervention groups

Intervention: Receiving 600 mg mexiltine tablets before abdominal surgery Control: receiving a placebo (one vitamin C tablet) before abdominal surgery

Main outcome variables

Postoperative pain score based on visual analog scale The amount of drug received during the first 24 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230405057824N1**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **retrospective**

Last update: **2023-09-05, 1402/06/14**
Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Abolfazl Jadidi davoudabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7719 0836

Email address

abolfazl.jadidi2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

2022-08-23, 1401/06/01

Actual recruitment end date

2023-02-20, 1401/12/01

Trial completion date

2023-03-20, 1401/12/29

Scientific title

Comparison of the effect of use of preoperative mexiletine tablets and placebo on reducing postoperative pain in patients undergoing abdominal surgery

Public title

Comparison of the effect of use of preoperative mexiletine tablets and placebo on reducing postoperative pain in patients undergoing abdominal surgery in Tehran Azad University hospitals in 2021-2023

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Informed and written consent Elective surgery Age 15-75 Absence of drug and alcohol abuse

Exclusion criteria:

Loss of consciousness Hemodynamic disorder Abnormal intraoperative bleeding The duration of the operation is more than 4 hours

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a list of all patients who were willing to participate in the study was first prepared, and after matching the patients who met the inclusion criteria, we assigned a number to each patient. We considered numbers 1 to 17 as group A and 18 to 34 as group B. Then, using an online random number table, the patients were placed in two groups (A group receiving mexiletine tablets and B group Vitamin C tablets).

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is a double-blind clinical trial (in order to make this study double-blind, the drugs used for the patients at the beginning of the study are A/B by the supervisor of the surgery department so that the clinical caregiver and the participants do not know the type of drug received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address

Tehran, Doktor Shariati St., Golhak Do Rahi, Amir Pabarja St., Aine Blvd., Corner of Gol Yakh St., Headquarters Building of Tehran Islamic Azad University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

IR.IAU.TMU.REC.1401.166

Health conditions studied

1

Description of health condition studied

Pain after abdominal surgery

ICD-10 code

T81.9

ICD-10 code description

Unspecified complication of procedure

Primary outcomes

1

Description

Pain

Timepoint

In recovery and at 6, 12, 24 hours after the operation, the amount

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The amount of narcotic (pethidine) received after the

operation

Timepoint

after surgery

Method of measurement

amount of drug used

Intervention groups

1

Description

One group received 600 mg mexilten tablets orally. The drug was administered two hours before the operation along with 50 cc of water. After the patients entered the operating room, the patients were under general anesthesia with the same drugs (propofol 2 mg per kg of patient weight or Nesdonal 5 mg per kg The patient's weight, midazolam 0.01 mg per kilogram of the patient's weight, fentanyl 2-3 macros per kilogram of the patient's weight and atrocurium 0.5 mg per kilogram of the patient's weight for induction and for maintenance of isoflurane 1-2% and oxygen N2o (50 50/) was used. For patients during surgery, 1 macro per kilogram of the patient's weight of fentanyl was repeated every hour, and then at the end of the surgery, a reverse muscle relaxant was performed with a mixture of neostigmine and atropine. Then after the surgery and in At 6, 12, 24 hours after the operation, the pain level of the patients was checked based on the VAS model, and in case of VAS>5, pethidine 30-50mg was injected intravenously to the patients, and at the end of the first day, the amount of narcotic used was recorded in the questionnaire by a nurse who had previously It was trained and registered.

Category

Treatment - Drugs

2

Description

One group received vitamin C tablets orally. The drug was administered two hours before the operation along with 50 cc of water. After patients enter the operating room, patients under general anesthesia with the same drugs (propofol 2 mg per kg of patient weight or Nesdonal 5 mg per kg of patient weight, midazolam 0.01 mg per kg of patient weight, fentanyl 2 - 3 macros per kilogram of patient weight and atrocurium 0.5 mg per kilogram of patient weight for induction and for maintenance, 1-2% isoflurane and oxygen N2o (50/50) were used. For patients during surgery, 1 macro per Every kilogram of the patient's weight, fentanyl was repeated every hour, and then at the end of the surgery, the reverse muscle relaxant was performed by a mixture of neostigmine and atropine. Then, after the surgery and at 6, 12, 24 hours after the operation, the pain level of the patients was measured according to the pattern VAS was checked and in case of VAS>5, pethidine 30-50mg was injected intravenously to the patients and at the end of the first day, the amount of narcotic used was recorded in the questionnaire by a trained nurse.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Abolfazl Jadidi davoud abadi

Street address

Tehran, Imam Hossein Square, the beginning of Damavand St

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1711734365

Phone

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booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Majid Naqipour

Street address

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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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

Abolfazl Jadidi davoudabadi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Medical student

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Abolfazl Jadidi davoud abadi

Position

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Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as the information related to the main outcome, can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It is accessible to all researchers

Under which criteria data/document could be used

All analysis and use of documentation is permitted

From where data/document is obtainable

The person responsible for the scientific responsibility of the study

What processes are involved for a request to access data/document

Contact the person responsible for the scientific accountability of the study

Comments