Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

76 patients who are candidates for surgery in hospitals affiliated with Islamic Azad University of Tehran are randomly divided into two groups. One hour before surgery, Mirtazapine will be given to the intervention group and placebo to the control group. After transferring the patients to the ward, the pain level of the patients is measured serially. We want to evaluate the preoperative effect of Mirtazapine administration on reducing postoperative pain (pain severity and duration of pain relief).

Protocol summary

Study aim
In this study, we are going to evaluate the preoperative effect of Mirtazapine administration on reducing postoperative pain, in hospitals affiliated with Islamic Azad University of Tehran.

Design
A controlled, single-arm, single-blind, phase 3 clinical trial on 76 patients. Convenience sampling method was used for sampling.

Settings and conduct
During this single-blind clinical trial study, 76 patients are selected from the patients who are candidates for surgery in the hospitals of Islamic Azad University of Tehran who met the criteria for entering the study, based on the convenience sampling method. After obtaining informed consent, the participants are blinded to study groups. Patients are randomly divided into two groups receiving Mirtazapine and the control group (placebo B-Complex). One hour before the surgery, the first group will be given a 30mg Mirtazapine tablet orally, and the second group will be given a placebo tablet by student under the supervision of an anesthesiologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are candidates for surgery Insensitivity to Mirtazapine Age between 25 and 50 years BMI between 20 and 25 ASA one or two Patient consent to conduct a clinical trial Criteria for not entering the study: Surgeries greater than an hour Emergency surgeries Pregnant women or the possibility of pregnancy Diabetic, cardiac, pulmonary and neurological patients Drug addiction

Intervention groups
Intervention group: Mirtazapine Control group: B-complex

Main outcome variables
Pain severity is measured serially 2, 6 and 12 hours after leaving the operating room.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221015056178N1**
Registration date: **2023-08-08, 1402/05/17**
Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**
Update count: **0**

Registration date
2023-08-08, 1402/05/17

Registrant information

Name
Mobina Niazi Nasihati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2230 8901

Email address
niazi.mobina@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-08-12, 1402/05/21

Expected recruitment end date
2023-09-12, 1402/06/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
76 patients who are candidates for surgery in hospitals affiliated with Islamic Azad University of Tehran are randomly divided into two groups. One hour before surgery, Mirtazapine will be given to the intervention group and placebo to the control group. After transferring the patients to the ward, the pain level of the patients is measured serially. We want to evaluate the preoperative effect of Mirtazapine administration on reducing postoperative pain (pain severity and duration of pain relief).

Public title
Evaluation of the preoperative effect of Mirtazapine administration on reducing postoperative pain, in hospitals affiliated with Islamic Azad University of Tehran in 2023

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are candidates for surgery Insensitivity to Mirtazapine Age between 25 and 50 years BMI between 20 and 25 ASA one or two Patient consent to conduct a clinical trial

Exclusion criteria:
Surgeries greater than an hour Emergency surgeries Pregnant women or the possibility of pregnancy Diabetic, cardiac, pulmonary and neurological patients Drug addiction

Age
From **25 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The intervention group receives mirtazapine with the aim of reducing pain after surgery, while the control group with the same goal is prescribed placebo under the name of B-complex. In this one-sided blind study, the researcher is aware of the recipients of mirtazapine and placebo, but the participants have been blinded to the study groups after obtaining informed consent. The members of the intervention and control groups were randomly selected and there are no special conditions for the classification of patients in this study. The purpose of blinding this clinical trial to the patients receiving the drugs is to investigate the analgesic effects of mirtazapine as best and accurately as possible and to avoid the involvement of confounding factors that affect the results of this study.

Placebo
Used

Assignment
Single

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 Islamic Azad University of Medical Sciences, Khaqani St., Shariati St.

City
Tehran

Province
Tehran

Postal code
1916893813

Approval date
2022-06-13, 1401/03/23

Ethics committee reference number
IR.IAU.TMU.REC.1401.069

Health conditions studied

1

Description of health condition studied
postoperative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of postoperative pain

Timepoint

2, 6 and 12 hours after leaving the operating room

Method of measurement

Visual Analogue Scale (facial experience)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mirtazapine

Category

Prevention

2

Description

Control group: B-Complex

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital

Full name of responsible person

Alireza Teymuri

Street address

Booali hospital, Damavand St., Imam Hosein Square

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Tehran

Province

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Postal code

1711734365

Phone

+98 21 3334 8036

Email

booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehrdad Gholamzad

Street address

Tehran Islamic Azad University of Medical Sciences, Khaqani St., Shariati St.

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mgholamzad@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

Mobina Niazi Nasihati

Position

Medical student/ internship

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mobina Niazi Nasihati

Position

Medical student/ internship

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available