

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Efficacy of Alprazolam pre medication on postoperative pain of elective abdominal surgery

Protocol summary

Study aim

Efficacy of preoperative alprazolam on postoperative pain in patients under elective abdominal surgery in Azad University hospitals

Design

106 people who underwent elective abdominal surgery were selected randomly, of which 53 were randomized in a double-blind, 0.5-mg alprazolam, and 53 placebo

Settings and conduct

In this interventional study conducted as a randomized clinical trial, 106 patients aged 20-60 years old with ASA, one or two, under elective abdominal surgery in Islamic Azad University hospitals for participation in Satisfaction Study They are not allergic to alprazolam, are available and are randomly selected and randomly divided into one of two groups receiving 0.5 mg oral alprazolam at night before surgery or placebo. And the amount of postoperative pain in them based on VAS in three times including recovery, first four hours and first 24 hours and the amount of analgesic used in the two groups were compared.

Participants/Inclusion and exclusion criteria

Entry requirements: 1. Elective surgery 2. Requests to participate in the study 3. American Statistical Classes 1 and 2 4. Age of between 20 and 60 years 5. No allergy to alprazolam 6. No drug addiction Non-arrival conditions: 1. Surgery for more than 3 hours 2. Non-cooperation of the patient due to delirium after surgery 3. Complicated surgery

Intervention groups

Giving Alprazolam tab to intervention group and placebo tab to control group of patients undergoing to elective intra-abdominal surgery

Main outcome variables

Study of postoperative pain in patients under elective abdominal surgery with and without taking Alprazolam tablet

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140916019198N3**

Registration date: **2019-03-31, 1398/01/11**

Registration timing: **prospective**

Last update: **2019-03-31, 1398/01/11**

Update count: **0**

Registration date

2019-03-31, 1398/01/11

Registrant information

Name

farshid gholami

Name of organization / entity

Islamic azad university , tehran medical branch

Country

Iran (Islamic Republic of)

Phone

+98 21 3318 7483

Email address

fgholami@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Alprazolam pre medication on postoperative pain of elective abdominal surgery

Public title

Alprazolam effect`s on acute pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elective abdominal surgery Consent letter for study A.S.A class I and II Age between 20 to 60 No allergy to Alprazolam No history of opium addiction

Exclusion criteria:

Operation time more than 3 hours Post operative delirium Complicated surgery

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

During preoperative visit of an anesthesiologist , The first patient who scheduled for elective intra-abdominal surgery will stay on a group by lion and for the rest of patient`s in between will be in two groups .

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients won`t know which group is . Drug prescriptive staff are unaware of division . Collector`s personnel are unaware of division too .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Medical Sciences Tehran Unit

Street address

Islamic Azad University of Medical Sciences Tehran

Unit.,atari moghaddam avenu , shahid khaghani avenu , shariati street

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

IR.IAU.TMU.REC.1395.255

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

intensity of pain

Timepoint

in recovery, 4 and 24 hours after surgery

Method of measurement

Visual Analogue Scale ruler

Secondary outcomes

1

Description

postoperative pain

Timepoint

in recovery, 4 and 24 hours after surgery

Method of measurement

Visual Analogue Scale ruler

Intervention groups

1

Description

Intervention group: "Elective subjects who were randomly assigned to receive alprazolam half a milligram a day before surgery"

Category

Prevention

2

Description

Control group: A number of elective abdominal patients randomly selected They received placebo before the operation

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Booali Hospital

Full name of responsible person

Farshid Gholami

Street address

Booali Hospital, Damavand street, Imam hossein square

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1711734365

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mehrdad Hashemian

Street address

Islamic Azad University of Tehran medical branch, Zargandeh, Gholhak

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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

Private

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

Farshid Gholami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information collection forms will be published.

When the data will become available and for how long

After the end of study

To whom data/document is available

Editor of the article's print magazine

Under which criteria data/document could be used

If needed and in order to prove the accuracy of the information

From where data/document is obtainable

Editor's office magazine

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

By a letter to the editor

Comments