

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparing the effect of clonidine with alprazolam on preoperative anxiety and hemodynamic variables in female patients candidates for abdominal surgery

Protocol summary

Study aim

Comparison of the effect of alprazolam and clonidine on patient's anxiety and hemodynamic variables before induction

Design

For the first group, oral alprazolam (0.5 mg) and for the second group, oral clonidine (1/2 tablet) administered the night before surgery. This clinical trial is double blind and randomised. Patients are completely randomized in the first and second intervention groups using the random numbers table. Transient Phase: Phase 2 on 60 persons

Settings and conduct

This study is performed on patients who have been admitted to the gynecology ward of Shahid Sadoughi Hospital in Yazd for abdominal surgery. Medications are given to the patient the night before the operation and anxiety and hemodynamic variables are evaluated in the morning of the operation. This study is double-blind and neither the researcher nor the patient knows the type of drug prescribed, so that the drugs are coded in two similar packages and the third person gives the drug to the patient based on the specified code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: including all female patients 18-60 years undergoing abdominal surgery for women referred to Shahid Sadoughi Hospital in Yazd. Exclusion criteria: Existence of moderate or severe systemic disease, History of taking sedatives and sedatives, Addiction to opioids, sedatives or psychotropic drugs, Patient dissatisfaction to participate in the study

Intervention groups

The first intervention group: oral administration of alprazolam 0.5 mg the night before surgery (n=30). The second intervention group: oral administration of clonidine 0.05 mg the night before surgery (n=30)

Main outcome variables

Their anxiety score based on VAS (0-10) and

hemodynamic variables (diastolic, systolic and mean arterial blood pressure, heart rate)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240511061740N1**

Registration date: **2025-01-13, 1403/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-13, 1403/10/24**

Update count: **0**

Registration date

2025-01-13, 1403/10/24

Registrant information

Name

Fateme Torabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

fatemetorabi@irct.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effect of clonidine with alprazolam on preoperative anxiety and hemodynamic variables in female patients candidates for abdominal surgery

Public title
Comparison of the effect of two tranquilizer oral drugs alprazolam and clonidin on patient,s anxiety before surgery and blood pressure and heart rate before induction of general anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Includes all female 18-60 years candidates for abdominal surgery referred to Shahid Sadoughi Hospital in Yazd
Exclusion criteria:
Existence of moderate to severe systemic disease history of using of sedative or tranquilizer drugs history of addiction to opioids or any sedative or psychotropic drugs patient disagreement for cooperation in this study

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly allocate 60 eligible applicants, we randomly divide them into two groups of 30 people. For this purpose, we use Random allocation software version 1.0 under Windows to create a sequence, and by using this software we make A list which is specified from 1 to 60 with group A or B treatment By Using this list, we give the first person who is eligible to enter the study, number one and the last person the number 60, then based on the random allocation list and by the software, it is determined which group A or B each person is in.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and researchers themselves are unaware of which medication the patient has received, in this way, the blank capsules with the same color and size and appearance are filled with powdered drugs , each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug is given to patients by a third party who is not involved in evaluating patients and recording results.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ali Ibn Abi Talib Medical School (AS), Islamic Azad University, Yazd Branch
Street address
Shahid khanbabaian Ave.,Artesh Blvd.,Shahiddashti Blv.
City
Yazd
Province
Yazd
Postal code
8949144181

Approval date
2024-02-04, 1402/11/15

Ethics committee reference number
IR.SSU.MEDICINE.REC.1402.334

Health conditions studied

1

Description of health condition studied
The effect of drug type on anxiety before induction of anesthesia

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
anxiety score

Timepoint
Before administration of study drug and before induction of anesthesia

Method of measurement
VAS(0-10)

2

Description
Systolic blood pressure

Timepoint
Before administration of study drug and before induction of anesthesia

Method of measurement
using monitoring device

3

Description

Diastolic blood pressure

Timepoint

Before administration of study drug and before induction of anesthesia

Method of measurement

using monitoring device

4

Description

Mean arterial pressure

Timepoint

Before administration of study drug and before induction of anesthesia

Method of measurement

using monitoring device

5

Description

heart rate

Timepoint

Before administration of study drug and before induction of anesthesia

Method of measurement

using monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the first group are given oral alprazolam (0.5 mg) the night before surgery.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in the second group are given oral clonidine (1/2 tablet) the night before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Dr.shokoofeh behdad

Street address

Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh,

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Web page address

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amirhooshang Mehrparvar

Street address

Central building of Yazd University of Medical Sciences, Bahonar Square.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Yazd University of Medical Sciences

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**

Yazd University of Medical Sciences

Full name of responsible person

Dr.shokoofeh behdad

Position

Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

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Other areas of specialty/work

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Email**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