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 clonidin 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 clonidin (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 18-60years 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 clonidin 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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+98 35 3822 0570

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, Yazd
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Fax
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sadoghi-hospital@ssu.ac.ir
Web page address
https://web.ssu.ac.ir/

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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8915887857
Phone
+98 35 3724 0171
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ah.mehrparvar@gmail.com
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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Yazd, Bahonar Square, the central building of Yazd University of Medical Sciences
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Person responsible for scientific inquiries

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Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd
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Person responsible for updating data

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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