

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The comparison of the effect of alprazolam and zaleplon on anxiety in the patients candidate for surgery

#### Protocol summary

##### Study aim

Comparison of the effect of oral administration of alprazolam and zaleplon on patient,s anxiety before surgery and hemodynamic variables before induction of anesthesia

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 66 patients. Random allocation software version 1.0 under Windows is used for randomization.

##### Settings and conduct

This study is performed on patients who have been admitted to the Kowsar 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: all female patients undergoing abdominal surgery referred to Shahid Sadoughi Hospital in Yazd. Non-inclusion criteria: Existence of moderate or severe systemic disease; History of taking sedatives and anti-anxiety drugs; Addiction to opioids, sedatives or psychotropic drugs; dissatisfaction to participate in the study

##### Intervention groups

Intervention group: In this group, 33 patients are randomly given 5 mg zalpon tablets orally the night before surgery. Control group: In this group, 33 patients were randomly assigned to take alprazolam 0.5 mg tablets orally the night before surgery.

##### Main outcome variables

Anxiety score based on VAS (0-10); Systolic blood pressure; diastolic blood pressure; mean arterial blood pressure; heart rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100102002963N33**

Registration date: **2021-10-18, 1400/07/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-18, 1400/07/26**

Update count: **0**

##### Registration date

2021-10-18, 1400/07/26

##### Registrant information

##### Name

Shekoufeh Behdad

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1822 1386

##### Email address

drbehdad@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-12, 1400/07/20

##### Expected recruitment end date

2022-01-10, 1400/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The comparison of the effect of alprazolam and zaleplon on anxiety in the patients candidate for surgery

**Public title**

The effect of two different tranquilizer drugs on anxiety in the patients candidate for surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Female patients Candidate for abdominal surgery  
Referred to Kowsar ward of Shahid Sadoughi Hospital in Yazd

**Exclusion criteria:**

Existence of moderate to severe systemic disease  
patient history of using of sedative or tranquilizer drugs  
history of addiction to opioids or any sedative or psychotropic drugs  
disagreement for cooperation in this study

**Age**

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

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomly allocate 66 eligible applicants, we randomly divide them into two groups of 33 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 66 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 66, then based on the random allocation list and by the software, it is determined which group A or B each person is in. 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 person who is not involved in evaluating patients and recording results.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and researchers themselves are unaware of which medication the patient has received, in this way, 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 person 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 Shahid Sadoughi University of Medical Sciences

**Street address**

Central building of Yazd University of Medical Sciences, Bahonar Square

**City**

Yazd

**Province**

Yazd

**Postal code**

8915887857

**Approval date**

2021-01-06, 1399/10/17

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1399.245

**Health conditions studied****1****Description of health condition studied**

The effect of drug 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**

Based on VAS(0-10)

**Secondary outcomes****1****Description**

Systolic blood pressure

**Timepoint**

Before administration of study drug and before induction of anesthesia

**Method of measurement**

Using monitoring device

**2****Description**

Diastolic blood pressure

**Timepoint**

Before administration of study drug and before induction of anesthesia

**Method of measurement**

Using monitoring device

**3****Description**

Mean arterial pressure

**Timepoint**

Before administration of study drug and before induction of anesthesia

**Method of measurement**

Using monitoring device

**4****Description**

Heart rate

**Timepoint**

Before administration of study drug and before induction of anesthesia

**Method of measurement**

Using monitoring device

**Intervention groups****1****Description**

Intervention group 1: Patients in this group are given oral alprazolam (0.5 mg) the night before surgery.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: Patients in this group are given oral zaleplon (5 mg) 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. Shekoufeh Behdad

**Street address**

Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh,

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Mirzaei

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Central building of Yazd University of Medical Sciences, Bahonar Square

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Mmirzaei@ssu.ac.ir

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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**

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. Shekoufeh 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 scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Shekoufeh Behdad

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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