

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

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

#### Protocol summary

##### Study aim

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

##### Design

For the first group, oral alprazolam (0.5 mg) and for the second group, oral zolpidem (5 mg) administered the night before surgery.

##### 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 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

(35 samples with oral administration of alprazolam and 35 samples with oral administration of zolpidem.

##### Main outcome variables

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100102002963N31**

Registration date: **2021-05-02, 1400/02/12**

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

Last update: **2021-05-02, 1400/02/12**

Update count: **0**

##### Registration date

2021-05-02, 1400/02/12

##### 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

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-07-21, 1400/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

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

### Public title

Comparison of the effect of two tranquilizer oral drugs alprazolam and zolpidem 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 patients undergoing abdominal surgery for women 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 **20 years** old to **60 years** old

### Gender

Female

### Phase

2

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In order to randomly allocate 70 eligible applicants, we randomly divide them into two groups of 35 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 70 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 70, 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, 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

Safaieh, Boulevard of the Shohadaie Gomnam

##### City

YAZD

##### Province

Yazd

##### Postal code

۸۹۱۵۸۱۳۱۳۵

#### Approval date

2021-03-15, 1399/12/25

#### Ethics committee reference number

IR.IAU.YAZD.REC.1399.067

## 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**

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

**Category**

Treatment - Drugs

### 2

**Description**

Patients in the second group are given oral zolpidem (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. Shokoofeh Behdad

**Street address**

Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh,

Yazd

**City**

Yazd

**Province**

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**Postal code**

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**Phone**

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**Email**

sadoghi-hospital@ssu.ac.ir

**Web page address**

<https://web.ssu.ac.ir/>

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Azad Islamic University Of Yazd

**Full name of responsible person**

Dr Seyed Mohammadreza Mortazavizadeh(Vice Chancellor for Research)

**Street address**

Boulevard of the Shohadaie Gomnam, Safaieh

**City**

Yazd

**Province**

Yazd

**Postal code**

8915813135

**Phone**

+98 35 3187 2200

**Fax**

+98 35 3821 5034

**Email**

info@iauyazd.ac.ir

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

Yes

**Title of funding source**

Azad Islamic University Of Yazd

**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**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr.Shokofe Behdad

**Position**

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

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Yazd, Bahonar Square, the central building of Yazd University of Medical Sciences

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**Postal code**

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**Email**

drbehdad@ssu.ac.ir

**Web page address**

<http://web.ssu.ac.ir>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr.Shokofe Behdad

**Position**

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

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email**

drbehdad@ssu.ac.ir

**Web page address**

<http://web.ssu.ac.ir>

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

Islamic Azad University

**Full name of responsible person**

Fatemeh Aref

**Position**

Professional doctoral medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Warriors Town - Asalat Street - 10th Alley

**City**

Yazd

**Province**

Yazd

**Postal code**

8915117117

**Phone**

+98 35 3821 0176

**Email**

fatemeharef7504@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The data obtained from the questionnaires are entered in the statistical software of SPSS version 21 and are statistically analyzed by the relevant statistical tests. The obtained statistical results and its comparison with the results of similar studies are published as a scientific article in one of the prestigious scientific journals.

**When the data will become available and for how long**

Access period starts from 1400

**To whom data/document is available**

The statistical results obtained from the statistical analysis of the data of this study will be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Only the results of statistical analysis of the data of this study will be available to university researchers

**From where data/document is obtainable**

Dr. Shekoufeh Behdad Professor of Anesthesiology,

Shahid Sadoughi University of Medical Sciences, Yazd.  
Mobile phone number: 09131514144 Email:  
behdad90@gmail.com

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

The applicant should send his / her application by e-mail or mobile phone and the requested documents will be sent to him / her within a few days.

**Comments**