

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

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Email

sadoghi-hospital@ssu.ac.ir

Web page address

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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

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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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Email

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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

Anesthesiology

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Email

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Web page address

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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

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Yazd

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8915117117

Phone

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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