

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Survey of the effect of oral zolpidem on hemodynamic signs and the patients Equilibrium in Stereotaxic surgeries.

#### Protocol summary

##### Study aim

The aim of this study was to determine and compare the hemodynamic parameters (systolic and diastolic blood pressure; mean blood pressure; heart rate; O<sub>2</sub> saturation) and the patients equilibrium during the stereotaxic surgeries in two groups of receiving zolpidem and placebo.

##### Design

The clinical trial is randomized, with controlled group, without parallel double blind groups.

##### Settings and conduct

Participants of elective stereotaxic surgery patients are selected after evaluating entry and exit criteria and are randomly assigned to receive Placebo and Zolpidem . Hemodynamic indices are recorded at the basic time(1hour before surgery), before anesthesia induction, 1, 3, 5,10,15 min after anesthesia, in the time of patient enter and every 15 min to the recovery.

##### Participants/Inclusion and exclusion criteria

Age between 20 - 65 years old; patients who consent to the informed consent to participate; ASA cslas 1,2; Non-inclusion criteria: use of sedative drugs;addiction to Alcohol; allergic reaction to drug; Parkinsons disease; obstructive sleep apnea; patients who have bradycardia.

##### Intervention groups

The once group receive 10 mg tablet of zolpidem 1 hour before surgery, The second group receive one tablet of placebo 1 hour before surgery, and Induction of anesthesia with 0.05 mg/kg Midazolam, 2 microgram/Kg Fentanyl.

##### Main outcome variables

Systolic blood pressure; diastolic blood pressure; mean blood pressure; heart rate; saturation of O<sub>2</sub>.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110528006617N6**

Registration date: **2021-07-07, 1400/04/16**

Registration timing: **prospective**

Last update: **2021-07-07, 1400/04/16**

Update count: **0**

##### Registration date

2021-07-07, 1400/04/16

##### Registrant information

###### Name

Mehrdad Masoudifar

###### Name of organization / entity

Esfahan University of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1268 2007

###### Email address

masoudifar@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-10, 1400/04/19

##### Expected recruitment end date

2021-08-22, 1400/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Survey of the effect of oral zolpidem on hemodynamic signs and the patients Equilibrium in Stereotaxic surgeries.

## Public title

The effect of oral zolpidem on hemodynamic indices and the patients Equilibrium in Stereotaxic surgeries.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age between 20 - 65 years old Patients who consent to the informed consent to participate in the study ASA class 1,2

### Exclusion criteria:

Use of sedative drugs Addiction to Alcohol Allergic reaction to drug Parkinsons disease Obstructive sleep apnea Patients who have bradycardia

## Age

From **20 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random function "Random Number Generation " of Excel software based on patient file number will be used for randomization. Patients file number were entered into Excel program and patients were divided into case and control groups based on the random button. In total, there were two groups of 64 people. In this case, the file number is entered in Excel program, then a random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want 32 people in each group. As a result, sequences 1 to 2 should be repeated 32 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 32 for repeating the sequence. In this way, 64 units will be produced.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

We produced tablet similar to Zolpidem, The once group received one tablet of Zolpidem 1 hour before surgery and the second group received one tablet of Placebo 1 hour before surgery. So the patients do not have any information about the intervention and the person who registered the information do not know which patient in which group is and the study has two blind side.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical sciences

##### Street address

Isfahan University Of Medical Science, Hezar Jarib Ave

##### City

Isfahan

##### Province

Isfahan

##### Postal code

7346181746

#### Approval date

2020-10-26, 1399/08/05

#### Ethics committee reference number

IR.MUI.MED.REC.1399.655

## Health conditions studied

### 1

#### Description of health condition studied

General anesthesia

#### ICD-10 code

T88.5

#### ICD-10 code description

Other complications of anesthesia

## Primary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

Basic time(one hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, in the time of patient enter to the recovery and every 15 min time of patient enter to the recovery.

#### Method of measurement

Mm-hg, sphygmomanometer

### 2

#### Description

Diastolic blood pressure

#### Timepoint

Basic time(one hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, in the time of patient enter to the recovery and every 15 min time of patient enter to the recovery.

#### Method of measurement

Mm-hg, sphygmomanometer

### 3

#### **Description**

Heart rate

#### **Timepoint**

Basic time(one hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, in the time of patient enter to the recovery and every 15 min time of patient enter to the recovery

#### **Method of measurement**

ECG monitor

### 4

#### **Description**

Mean arterial pressure

#### **Timepoint**

Basic time(one hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, in the time of patient enter to the recovery and every 15 min time of patient enter to the recovery

#### **Method of measurement**

Mm-hg, sphygmomanometer

### 5

#### **Description**

O2 saturation

#### **Timepoint**

Basic time(one hours before surgery), before anesthesia induction, 1,3,5,10,15 min after anesthesia, in the time of patient enter to the recovery and every 15 min time of patient enter to the recovery

#### **Method of measurement**

O2 saturation percentage , pulse oximeter device

### 6

#### **Description**

Surgeon Satisfaction

#### **Timepoint**

End of the surgery

#### **Method of measurement**

Likert Scale

### 7

#### **Description**

Patient Satisfaction

#### **Timepoint**

End of the surgery

#### **Method of measurement**

Likert Scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Initially, personal consent is obtained from the patients. This group receive 10 mg tablet of zolpidem 1 hour before surgery, Then the patient is placed on the operating bed and standard monitoring devices including pulse oximetry, capnography are attached and Induction of anesthesia with 0/05mg/kg Midazolam, 2 microgram/Kg Fentanyl .

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Initially, personal consent is obtained from the patients. This group receive tablet of placebo 1 hour before surgery, Then the patient is placed on the operating bed and standard monitoring devices including pulse oximetry, capnography are attached and Induction of anesthesia with 0/05mg/kg Midazolam, 2 microgram/Kg Fentanyl .

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra hospital

##### **Full name of responsible person**

Mehrdad Masoudifar

##### **Street address**

Alzahra hospital, Sofe Blvd, Shahid Keshvari Highway

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174675731

##### **Phone**

+98 31 3620 2020

##### **Email**

alzahra@mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Shaghayegh Haghjoo Javanmard

##### **Street address**

Isfahan University of Medical Science, Hezar Jarib Ave

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

7346181746

**Phone**

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**Email**

sh\_haghjoo@med.mui.ac.ir

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehrdad Masoudifar

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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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