Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Survery of the effect of oral zolpidem on hemodinamic signs and the patients Equlibrium 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; O2 saturation) and the patients equilibrium during the steriotaxic 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 Fentanil.

Main outcome variables
Systolic blood pressure; diastolic blood pressure; mean blood pressure; heart rate; saturation of O2.

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
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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
Survery of the effect of oral zolpidem on hemodinamic signs and the patients Equlibrium in Stereotaxic surgeries.

Public title
The effect of oral zolpidem on hemodinamic indicies and the patients Equlibrium 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 ist 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
Isfehan
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 pessure
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 perating bed and standard monitoring devices including pulsoximetry,capnography are attached and Induction of anesthesia with 0/05mg/kg Midazolam, 2 microgram/Kg Fentanil .
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 perating bed and standard monitoring devices including pulsoximetry,capnography are attached and Induction of anesthesia with 0/05mg/kg Midazolam, 2 microgram/Kg Fentanil .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Mehrdad Masoudifar
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Alzahra hospital, Sofe Blvd, Shahid Keshvari Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
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
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Person responsible for scientific inquiries

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Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
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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