

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Compare the effectiveness of Lavender essential oil and Alprazolam on anesthesia and hemodynamic parameters during general anesthesia process

#### Protocol summary

##### Study aim

Compare the effect of Lavender essential oil and Alprazolam on deep of anesthesia and thermodynamic parameters during general anesthesia process

##### Design

Based on the inclusion criteria, patients will divide into 3 control and intervention groups (1 and 2) by simple random allocation method. The interventions in the groups are double-blind, that is, the pre-medication is given to the patient by the researcher, and the person assessing the depth of anesthesia and the statistical analyst will be unaware of the type of interventions.

##### Settings and conduct

The study will be performed in the hospital setting, between the hours of 7-8 am (2-3 hours before surgery) for group 1, 0.5 mg oral alprazolam, and for group 2, Three drops of lavender on a clean cloth or dressing is inhaled inhaled for 15-20 minutes by patients and. Routine medications administered to the patient include midazolam 0.02 mg / kg, fentanyl 2 ug / kg, or sufenta 0.2 ug / kg for anesthesia initiation.

##### Participants/Inclusion and exclusion criteria

Patients choice in class I anesthesia, age group 15-60 years with no serious disease.

##### Intervention groups

In intervention group 1 (alprazolam), in intervention group 2 (lavender aromatherapy) and in the non-intervention control group, only vital signs and depth of anesthesia are evaluated.

##### Main outcome variables

In this study, vital signs such as heart rate, blood pressure (systolic, diastolic, and mean arterial pressure MAP), respiratory rate and SPO2 level will be assessed before administration of pre-medication, before anesthetic, and concurrent with anesthesia(per operative) and 5 minutes after surgery. Depth of anesthesia during surgery for 3 times (starting time of

surgery, mid-surgery and finishing the last part of surgery) and also after surgery.

#### General information

##### Reason for update

To facilitating study process, because the use of regional anesthesia methods in lower extremity surgeries, the number of patients for sampling was very limited. The spread of the Covid-19 disease has caused the suspension of sampling and intervention for almost two years. The update was done after consulting with legal supervisors and using the experiences of anesthesiologists without affecting the scientific quality of the study.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191208045659N1**  
Registration date: **2019-12-28, 1398/10/07**  
Registration timing: **prospective**

Last update: **2022-08-12, 1401/05/21**

Update count: **1**

##### Registration date

2019-12-28, 1398/10/07

##### Registrant information

###### Name

Sefollah Alaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3365 4190

###### Email address

alaei@semums.ac.ir

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2020-01-04, 1398/10/14

### Expected recruitment end date

2022-11-05, 1401/08/14

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

Compare the effectiveness of Lavender essential oil and Alprazolam on anesthesia and hemodynamic parameters during general anesthesia process

## Public title

effect of Lavender essential oil and Alprazolam on anesthesia and hemodynamic parameters during general anesthesia process

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Class I and II Anesthesia, Age group 15-60 years Not have serious illnesses and problems affecting body function and thermodynamics such as diabetes and cardiovascular disease

### Exclusion criteria:

History of mental illness or brain injury, current use of sedatives, opiates, psychotropics drugs, patients who do not cooperate, history of allergies or olfactory problems, pre- and inoperative body temperature rise, use of medications effective on sleep (such as phenobarbital)

## Age

From **15 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using random number tables (random blocks A, B, C), patients are placed in one of intervention groups 1 (alprazolam), intervention group 2 (lavender scent) and group 3 (control group)

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Premeditation therapy with alprazolam for group 1 and aromatherapy for group 2, will be performed by the researcher in the morning of surgery day. The person who evaluating the depth of anesthesia and the

statistical analyst does not know the type of pre-medication received by the patient or whether he is in the intervention or control group

## Placebo

Not used

## Assignment

Parallel

## Other design features

The current study aims to help expand the use of non-pharmacological methods in the anesthesia and surgery process.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Semnan University of Medical Sciences Ethics Committee

##### Street address

Damghan Road, Semnan University of Medical Sciences

##### City

Semnan

##### Province

Semnan

##### Postal code

3514993437

#### Approval date

2019-11-18, 1398/08/27

#### Ethics committee reference number

IR.SEMUMS.REC.1398.202

## Health conditions studied

### 1

#### Description of health condition studied

Fractures of various organs that are surgically repaired under anesthesia

#### ICD-10 code

S72.04

#### ICD-10 code description

Fracture of base of neck of femur

### 2

#### Description of health condition studied

Femoral neck fracture

#### ICD-10 code

S72.043

#### ICD-10 code description

Displaced fracture of base of neck of unspecified femur

### 3

#### Description of health condition studied

Fracture of the bones of the right hand

**ICD-10 code**

S62.91XA

**ICD-10 code description**

Unspecified fracture of right wrist and hand

**4**

**Description of health condition studied**

Fracture of the bones of the left hand

**ICD-10 code**

S62.92XA

**ICD-10 code description**

Unspecified fracture of right wrist and hand

**5**

**Description of health condition studied**

Abdominal and gastrointestinal surgeries

**ICD-10 code**

S39.91XA

**ICD-10 code description**

Abdominal surgeries

**Primary outcomes**

**1**

**Description**

The depth of anesthesia is evaluated peroperation and immediately after surgery.

**Timepoint**

Depth of anesthesia during surgery for 3 times will be assessed. The assessment time is in starting of surgery, mid-surgery and finishing the last part of surgery and also after surgery, 5 minutes after being placed on the recovery bed .

**Method of measurement**

Depth of anesthesia is measured by the Bispectral index (BIS) device. The patient's blood pressure is also measured using a digital blood pressure monitor

**Secondary outcomes**

**1**

**Description**

Vital sign include the patient's breathing, pulse rate and blood pressure measured by the assessor as well as with the help of a digital Sphygmomanometer.

**Timepoint**

Vital signs will be measured before prescription medication, 5 minutes after surgery, before anesthesia, at the time of surgery, mid-surgery, and after the last part of the surgical intervention. . It will be also measured 5 minutes after surgery on the recovery bed.

**Method of measurement**

By the assessor as well as with the help of a digital Sphygmomanometer

**Intervention groups**

**1**

**Description**

2-3 hours before surgery premed will be administrated. For group 1, the dose of oral alprazolam is 0.5 mg.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: 3 drops of lavender that is poured on a clean cloth or gauze and inhaled for 15-20 minutes.

**Category**

Treatment - Drugs

**3**

**Description**

Control group: As a control group, they receive only routine medications

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kosar Hospital

**Full name of responsible person**

Sefollah Alaei

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Semnan 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**

Semnan 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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Semnan University of Medical Sciences

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**Person responsible for updating data**

**Contact**

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Semnan University of Medical Sciences

**Full name of responsible person**

Sefollah Alaei

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## 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**

Undecided - It is not yet known if there will be a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

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

Baseline data of participants' such as age, sex, and kind of disease, intervention, and outcomes could be available to others through the publication of articles

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

It is available to everyone indefinitely by publishing the article

### **To whom data/document is available**

research center of Semnan University of Medical Sciences and researchers in the field of anesthesiology and intensive care could access the anonymous documentation by providing appropriate reasons.

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

The main finding data will be available to the public through articles. More detailed data will be made available to researchers and specialists through correspondence with the research team

### **From where data/document is obtainable**

By contact with the Correspond author in the published articles

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

Introduce himself and mentioning personal, professional and organizational characteristics as well as the reasons for accessing to more detailed information and how to use this information.

### **Comments**

It seems that through the publication of the articles, the main research findings can be available to practitioners and researchers in anesthesiology and intensive care fields.