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 facilating study process, because the use of regional anesthesia methods in lower extermity 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

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Iran (Islamic Republic of)

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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
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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

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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

Person responsible for general inquiries

Contact

Name of organization / entity
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.