Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effect of aromatherapy with lavender and cloves on headache severity caused by spinal anesthesia in patients undergoing urological surgery in Bahonar Hospital in Kerman in 2021-2022

Protocol summary

Study aim
Comparison of the effect of aromatherapy with cloves and lavender on pain caused by spinal anesthesia in patients undergoing urological surgery in Bahonar Hospital in Kerman in 2021-2022

Design
Patients who meet the inclusion criteria were selected by available sampling method and randomly divided into three groups: aromatherapy with lavender, aromatherapy with cloves and control.

Settings and conduct
The research environment will be Shahid Bahonar Hospital. First, the demographic and background information questionnaire is completed using the file and, if necessary, the patient for each sample. After transferring the patient to recovery, pain intensity is measured and recorded in each group based on visual scale. Then, the members of the intervention group undergo aromatherapy. There is no intervention in the control group and they receive routine care as usual.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60 years, no previous history of spinal anesthesia, No sensitivity to aromatic substances, No history of infection Respiratory diseases such as asthma, sinus disorders and rhinitis and not using aromatherapy for the patient for a week before the intervention Exclusion criteria: re-spinal anesthesia and the emergence of skin and respiratory allergies in the patient

Intervention groups
Intervention group: A sterile gas with 3 drops of fragrance (lavender and cloves) is impregnated with 5% concentration and placed at a distance of 10 cm from the patient's nose and the patient inhales it for 5 minutes and this again 8 Repeat 24 hours later. Control group: In patients in the control group, inhalation of gas impregnated with normal saline is performed and 8 and 24 hours after surgery for the desired variable.

Main outcome variables
Headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211124053172N1**
Registration date: **2022-01-01, 1400/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-01, 1400/10/11**
Update count: **0**

Registration date
2022-01-01, 1400/10/11

Registrant information

Name
Atena Samareh Fekri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3211 3491

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atena.samarehfekri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-11, 1400/09/20

Expected recruitment end date
2022-05-10, 1401/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of aromatherapy with lavender and cloves on headache severity caused by spinal anesthesia in patients undergoing urological surgery in Bahonar Hospital in Kerman in 2021-2022

Public title
The effect of aromatherapy with lavender and cloves on headache severity caused by spinal anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
No previous history of spinal anesthesia Classes 1 and 2 based on ASA classification Lack of blindness and deafness due to the use of visual pain scale No history of migraine and chronic headache Lack of sensitivity to aromatic substances No history of respiratory disease such as asthma, sinus disorders and rhinitis Do not use aromatherapy for the patient for a week before the intervention No mental health problems with a doctor's diagnosis Perform anesthesia by an anesthesiologist with a needle of the same size with just one attempt No coagulation disorders
Exclusion criteria:
Perform re-spinal anesthesia Induction of general anesthesia Having an absolute rest of more than 8 hours Emergence of skin and respiratory allergies in the patient Preoperative headache pregnant women
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who met the inclusion criteria were selected by convenience sampling method and randomly divided into three groups: aromatherapy with lavender, aromatherapy with cloves and control. To compile a random list, the online software https://www.sealedenvelope.com/simple-randomiser/v1/lists will be used, the size of the blocks will be 6 and the two variables of gender (male / female) and age (Less than 30 years old) will be considered as classes when creating a random list.
Blinding (investigator's opinion)
Single blinded
Blinding description
At the beginning of the intervention, patients in the intervention group separately in the recovery so that other patients are not exposed to inhalation of the drug by one of the operating room staff who is not present in the study, A sterile gas with 3 drops of fragrance with the desired concentration of 5% (lavender or clove) is impregnated and placed at a distance of 10 cm from the patient's nose and the patient inhales it for 5 minutes This is repeated 8 hours and 24 hours later, and 30 minutes after the second and third interventions, the amount of pain is measured and recorded. The second intervention (8 hours after the operation) and the third (24 hours after the operation) are performed there due to the transfer of the patient to the urology department.In patients in the control group, inhalation of gas impregnated with normal saline is performed and 8 and 24 hours after surgery are examined for the desired variable. In the control group, no intervention is performed.And receive routine care as usual. In addition, all medications received by patients in a total of 24 hours after surgery are recorded in all three intervention and control groups.Also, the environmental conditions, including closing the doors and windows, minimizing the pleasant and unpleasant odors in the ward, are equalized for the three groups. Also, the two intervention groups were placed in separate rooms.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kerman University of Medical Sciences
Street address
campus of Kerman University of Medical Sciences, The beginning of Haft Bagh Alavi axis
City
Kerman
Province
Kerman
Postal code
76169-13555
Approval date
2021-11-08, 1400/08/17
Ethics committee reference number
IR.KMU.REC.1400.495

Health conditions studied

1

Description of health condition studied
patients undergoing urological surgery

ICD-10 code
ICD-10 code description
urological surgery

Primary outcomes

1

Description
Pain score on the VAS scale
Timepoint
Pain measurement at the beginning of the study (before the intervention) and 30 minutes after the second intervention (8 hours after surgery) and the third (24 hours after surgery)
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: At the beginning of the intervention, patients in the intervention group separately in recovery so that other patients are not exposed to inhalation of the drug, a sterile gas with 3 drops of lavender with a concentration of 5% impregnated and placed 10 cm from the patient's nose It is taken and the patient inhales it for 5 minutes, and this is repeated 8 hours and 24 hours later, and 30 minutes after the second and third interventions, the amount of pain is measured and recorded. The second intervention (8 hours after the operation) and the third (24 hours after the operation) are performed there due to the transfer of the patient to the urology department.
Category
Prevention

2

Description
Intervention group 2: At the beginning of the intervention, patients in the intervention group separately in recovery so that other patients are not exposed to inhalation of the drug, a sterile gas with 3 drops of cloves with a concentration of 5% impregnated and placed 10 cm from the patient's nose It is taken and the patient inhales it for 5 minutes, and this is repeated 8 hours and 24 hours later, and 30 minutes after the second and third interventions, the amount of pain is measured and recorded. The second intervention (8 hours after the operation) and the third (24 hours after the operation) are performed there due to the transfer of the patient to the urology department.
Category
Prevention

3

Description
Control group: There is no intervention in the control group and they receive routine care as usual.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Hospital, Kerman
Full name of responsible person
Atena Samarehfekri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Atena Samarehfekri
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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
Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Atena Samareh Fekri

Position

University employee

Latest degree

Master

Other areas of specialty/work

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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