Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of aromatherapy with lavender and Clary sage on Percutaneous nephrolithotomy postoperative pain, hemodynamic status, nausea and vomiting

Protocol summary

Study aim
Comparison of the effect of lavender and sage scent on pain, hemodynamic status and nausea and vomiting in patients undergoing extraction of cutaneous kidney stones from Bahonar hospital in Kerman in 1397

Design
Clinical trials has two intervention groups and one control group. A total of 90 people who had surgery on Percutaneous nephrolithotomy in Kerman Bahonar Hospital were divided into three groups by block accident. This study is without blindness.

Settings and conduct
Sampling is carried out at the Bahonar Arch Hospital in the urological department. Individuals in two intervention groups, each with an intervention. This study is without blindness.

Participants/Inclusion and exclusion criteria
Entry requirements: Patients undergoing Percutaneous nephrolithotomy؛ Age 18-65 years old؛ Classification ASA Class I and II Exit Conditions: Coagulation disorder؛ History of migraine and chronic headache؛ History of allergy to medicinal herbs؛ Meniere syndrome؛ Respiratory problems during surgery؛ Sensitiveness to aromatic substances؛ A history of respiratory disease such as asthma, sinusitis and rhinitis؛ Use hypnotics, sedative medicines or benzodiazepines a week before the onset of intervention؛ Use the Aromatherapy for the patient within a week before the intervention begins؛ Having psychological problems with doctor's diagnosis؛

Intervention groups
In this study, there are three groups of people, which is a control group and the other two receive each intervention. Interventions include scent of lavender and seaweed

Main outcome variables
Evaluation, pain, hemodynamic status, and vomiting nausea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180321039135N1**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**
Update count: **0**

Registration date
2018-09-04, 1397/06/13

Registrant information

Name
Mojdeh Amirhossaini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3281 0537

Email address
m.amirhossaini@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of aromatherapy with lavender and Clary sage on Percutaneous nephrolithotomy postoperative pain, hemodynamic status, nausea and vomiting

Public title
Study the effect of aromatherapy on patients after Percutaneous nephrolithotomy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing Percutaneous nephrolithotomy Age 18-65 ASA classification I , II

Exclusion criteria:
Coagulation disorder History of migraine and chronic headache History of allergy to medicinal herbs Meniere syndrome Respiratory problems during surgery Sensitiveness to aromatic substances A history of respiratory disease such as asthma, sinusitis and rhinitis Use hypnotics, sedative medicines or benzodiazepines a week before the onset of intervention Use the Aromatherapy for the patient within a week before the intervention begins Having psychological problems with doctor's diagnosis

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocking method was used for randomization. For random allocation, the participants were divided into three groups, with a sample number of 30 in each group, randomization method was used. For this purpose, 15 blocks of 6 were used. In this method, the intervention and control groups are divided into three groups, A, B, C. Possible blocks were AABBCC, ABCABC, BACABC, CCBBAA, ABCCBA, CBACBA, numbers 1 to 6 were assigned to each of these blocks, respectively. Then the numbers from 1 to 6 were extracted from the random numbers table. (Obviously, in the case of extraction of the zero number, the number from 7 to 9 was again retrieved from the random number extraction), and it is selected in accordance with the extracted number of a block to identify 15 blocks. In the same way as the blocks are obtained, a list of 90 will be provided and the participants will be assigned respectively two groups A, B, and C respectively.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
Kerman University Of Medical Sciences, Medical University Campus, Haft-Bagh Highway

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2018-07-11, 1397/04/20

Ethics committee reference number
IR.KMU.REC.1397.084

Health conditions studied

1

Description of health condition studied
Percutaneous Nephrolithotomy (PCNL)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
systolic blood pressure average

Timepoint
At first and before the intervention, a blood pressure is measured once. The first intercourse is performed immediately after surgery in the operating room. Second and third interventions are performed 3 and 6 hours after the operation. In each intervention, the blood pressure is doubled at a time interval of 5 to 10 minutes, and then the average is recorded. All measurements related to blood pressure are performed 30 minutes after the intervention

Method of measurement
Digital Sphygmomanometer

2

Description
Diastolic blood pressure average

Timepoint
At first and before the intervention, a Diastolic blood pressure is measured once. The first intercourse is performed immediately after surgery in the operating room. Second and third interventions are performed 3 and 6 hours after the operation. In each intervention, the blood pressure is doubled at a time interval of 5 to 10 minutes, and then the average is recorded. All measurements related to blood pressure are performed 30 minutes after the intervention
Method of measurement
Digital Sphygmomanometer

Secondary outcomes

1

Description
Incidence of nausea and vomiting
Timepoint
The first intermission is performed immediately after surgery in the operating room. Second and third interventions are performed 3 and 6 hours after the operation. All measurements for nausea and vomiting are performed 30 minutes after intervention.
Method of measurement
Visual analog scale (VAS)

2

Description
Intensity of pain
Timepoint
The first intermission is performed immediately after surgery in the operating room. Second and third interventions are performed 3 and 6 hours after the operation. All measurements for nausea and vomiting are performed 30 minutes after intervention.
Method of measurement
Visual pain assessment scale (VAS)

Intervention groups

1

Description
Intervention group 1: On each person, three interventions are performed after the operation. This is the first time after surgery in the operating room. The second and third turns are performed at 3 and 6 hours after surgery in the urological department. The intervention is stained with a sterile gas with 3 drops of aromatics (lavender) and placed at a distance of 10 cm from the nose of the patient and we instruct him to inhale for 5 minutes and 30 minutes after the intervention. We measure pain, hemodynamic status, and nausea in the patient's vomiting.All measurements for physiological indicators are performed at intervals of 5 to 10 minutes each time, and the average is recorded.
Category
Treatment - Other

2

Description
Intervention group 2: On each person, three interventions are performed after surgery. This is the first time after surgery in the operating room. The second and third turns are performed at 3 and 6 hours after surgery in the urological department. The intervention is stained with a 3-drops of aromatics (sage) and placed at a distance of 10 cm from the patient's nose and we instruct him to inhale for 5 minutes and 30 minutes after the intervention We measure the pain, hemodynamic status, and nausea in the patient's vomiting. All measurements for physiological indicators are performed at intervals of 5 to 10 minutes each time, and the average is recorded.
Category
Treatment - Other

3

Description
Control group: In the control group, blood pressure is taken from each person in three times and the relevant questionnaire is completed. The first turn is done after the work is done in the operating room. The second and third turns are performed at the 3rd and 6th hour after surgery in the urological department. All measurements for physiological indicators are performed at intervals of 5 to 10 minutes each time, and the average is recorded.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Hospital of Kerman
Full name of responsible person
Mojdeh Amirhossaini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman 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
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
Mojdeh Amirhossaini
Position
student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is still no plan to develop a program for sharing the data. According to the above sampling data time, the

study will be completed by that time

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available