Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of aromatherapy with rose on anxiety and pain of patients before and after Endoscopic lithotripsy procedure

Protocol summary

Study aim
Determining the effect of aromatherapy with rose flowers on the anxiety and pain of patients before and after endoscopy urology surgery

Design
Experimental study of a three-blind clinical trial

Settings and conduct
This research is in the form of a randomized clinical trial, which will be conducted with permission from Shiraz University of Medical Sciences and receiving the code of ethics on 120 patients who are candidates for stone-breaking surgery by endoscopic method at Ali Asghar and Shahid Faqihi Hospital in Shiraz. In this study, patients were placed in two intervention and control groups through available sampling based on the selection criteria and then through random allocation through a table of random numbers.Visual Analogue Scale (VAS) and Spielberger questionnaire are used to collect data. In both groups, the intervention and control of pain and anxiety will be evaluated in three stages before aromatherapy and before and after surgery using VAS tool and Spielberger questionnaire. The intervention in the intervention group will be carried out in three stages 6 hours before the operation and in the recovery room after the operation and 6 hours after the operation with three drops of rose essential oil on cotton at a distance of 10 cm from the patient's nose. All the above measures with distilled water in The control group will also be done and finally the results of the two groups will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: willingness to participate in the study; enjoying mental health; hemodynamic stability; not using anti-anxiety and painkillers; olfactory health; no history of food and seasonal allergies.

Intervention groups
Patients will be randomly divided into two groups; the first group will inhale rose essence, and the second group will inhale distilled water.

Main outcome variables
Pain and anxiety before and after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100919004775N14**
Registration date: **2022-11-16, 1401/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-16, 1401/08/25**
Update count: **0**

Registration date
2022-11-16, 1401/08/25

Registrant information

Name
Zinat Mohebbi

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with rose on anxiety and pain of patients before and after Endoscopic lithotripsy procedure

Public title

The effect of aromatherapy with rose flowers on pain and anxiety before and after surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Enjoying mental-psychological health No hearing or speech impairment Hemodynamic stability Absence of chronic pain No use of anti-anxiety and pain relievers Olfactory health No history of food and seasonal allergies

Exclusion criteria:

Addicted people or those who use narcotic drugs or painkillers for a long time Patients who need medication or measures other than routine care during surgery to eliminate complications and reduce pain intensity Expression of disapproval to continue the research

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher will select the samples according to the conditions of entering the study and based on the purpose, in the form of available sampling. For randomization, permutation blocks will be used to assign people to two control and intervention groups. The samples are selected from two centers and are allocated in these classes by the method of alternating blocks of samples. Based on the sample size and the number of groups, 60 people will be allocated in each group and then the samples will be allocated to 5 blocks of 6 in each center. The random allocation list is prepared by online software on the web.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the information will be informed that they will participate in a study, but they did not realize that they are in the control group or in the intervention group. The help of the researchers who conduct the intervention, I do not know which group is the experimental group, part of the group, and which group is the control group. Bottles of rose essential oil and placebo will be introduced with the help of researchers in the form of drug A and drug B. Also, helping the patients who evaluates the pain and the doctor before and after the intervention, I don't know which patient is in the intervention group and which patient is in the control group.For the one who will analyze the results, the intervention and control group will be introduced as group A and B. For the research assistant who will carry out the intervention, rose essence will be introduced as drug A and distilled water as drug B. In addition, during the study, the patients in the intervention group and the control group will be tried to be in separate rooms. On the other hand, the patients will not want to know whether they are in the control group or the control group.

Placebo

Used

Assignment

Parallel

Other design features

Experimental study of a three-blind clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Faculty of Nursing and Midwifery of Shiraz University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Namazi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2022-10-08, 1401/07/16

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.064

Health conditions studied

1

Description of health condition studied

Pain before and after surgery

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description
Pain before and after surgery
Timepoint
6 hours before the operation - immediately after the intervention - 6 hours after the operation
Method of measurement
Visual analog Scale

2

Description
Anexiety before and after surgery
Timepoint
6 hours before the operation - immediately after the intervention - 6 hours after the operation
Method of measurement
Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:All patients will complete relevant questionnaires (demographics, pain intensity and anxiety) before aromatherapy. In the intervention group, 6 hours before the surgery, the researcher will soak the cotton with three drops of rose essential oil (provided by Barich Essential Oil Company, Kashan) and install it at a distance of 10 cm on the patient's clothes with a plastic pin, and then ask him You can breathe normally. When the patient is waiting in the operating room and in the preparation room before the operation,the severity of their pain and anxiety is also completed once again by the project partner. In the operating room, all patients are anesthetized by spinal anesthesia with Markain 10 mg and spinal needle number 25.After completing the surgery and reconnecting with the patients in the recovery room, the researcher will apply 3 drops of rose essential oil on cotton and place it on the patient's clothes at a distance of 10 cm, and he will be asked to wait for 6 Breathe normally. 6 hours after the surgery, the researcher will again measure the pain intensity and the level of anxiety of the patients using the mentioned questionnaires
Category
Treatment - Other

2

Description
Control group: All patients will complete relevant questionnaires (demographics, pain intensity and anxiety) before aromatherapy. In the intervention group, 6 hours before the surgery, the researcher will soak the cotton with distilled water and attach it to the patient's clothes with a plastic pin at a distance of 10 cm, and then he will be asked to breathe normally. When the patient is waiting in the operating room and in the preparation room before the operation, the intensity of their pain and anxiety is also completed again by the project partner.In the operating room, all patients are anesthetized by spinal anesthesia with Markain 10 mg and spinal needle number 25. After the surgery is completed and reconnecting with the patients in the recovery room, the researcher again smears the distilled water on the cotton and It will be installed on the patient's clothes at a distance of 10 cm and he will be asked to breathe normally for 6 hours. 6 hours after the surgery, the researcher will again measure the pain intensity and the level of anxiety of the patients using the mentioned questionnaires
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faqihi and Aliasghar Hospital
Full name of responsible person
Maryam Mohit
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Sponsors / Funding sources

1

Sponsor
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Grant name

26218 25/07/1401

Grant code / Reference number

26218

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Chancellor for Research and Technology of Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Mohit

Position

Surgical Technologist

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

Other areas of specialty/work

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Associate Professor

Latest degree

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

We do not have data yet

When the data will become available and for how long

Access period starts after publish the article

To whom data/document is available

All people

Under which criteria data/document could be used

For Operation Room Personnel

From where data/document is obtainable

Corresponding Author

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

Is email to Corresponding Author.

Comments