Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating of the Effect of Aromatherapy with lavender on the Satisfaction, Pain and Physiological indicators of Patients undergoing endoscopic retrograde cholangiopancreatography (ERCP)

Protocol summary

Study aim

Determining the effect of aromatherapy with lavender on the level of satisfaction, pain and physiological indicators of patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) admitted to the selected hospitals of Shahid Beheshti University of Medical Sciences.

Design

A parallel randomized clinical trial with control and intervention groups, a blind strain on 80 patients. For randomization, the random number function table of Excel software will be used.

Settings and conduct

The place of intervention is the gastroenterology department of the hospital. In order to reduce the communication between the two experimental and control groups, the intervention will be carried out in separate rooms. The method of performing aromatherapy will be that four drops of lavender essential oil with a concentration of 2% will be dripped on sterile gauze and placed on the chest of patients in the intervention group, and they will be asked to breathe for at least 30 minutes before Perform the procedure and inhale it. In the control group, normal saline is used.

Participants/Inclusion and exclusion criteria

Entry conditions: not having a history of drug sensitivity, having the necessary cooperation to perform the procedure, not receiving painkillers before and after the procedure in the control and intervention groups, the same anesthesia protocol. Not having a smell problem
Do not enter: any allergy to lavender

Intervention groups

The method of performing aromatherapy will be that four drops of lavender essential oil with a concentration of 2% will be dripped on sterile gauze and placed on the chest of patients in the intervention group, and they will be asked to breathe for at least 30 minutes before Perform the procedure and inhale it. In the control group, normal saline is used.

Main outcome variables

satisfaction; the pain; Physiological indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221227056941N1**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **prospective**

Last update: **2023-02-01, 1401/11/12**
Update count: **0**

Registration date

2023-02-01, 1401/11/12

Registrant information

Name

Roya Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 4329

Email address

rajabiroya00@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-05, 1402/01/16

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating of the Effect of Aromatherapy with lavender on the Satisfaction, Pain and Physiological indicators of Patients undergoing endoscopic retrograde cholangiopancreatography (ERCP)

Public title

Investigating of the Effect of Aromatherapy with lavender on the Satisfaction, Pain and Physiological indicators of Patients undergoing endoscopic retrograde

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of drug sensitivity Having the necessary cooperation to perform the procedure Not receiving analgesics before and after the procedure in the control and intervention groups The same anesthesia protocol Not having a smell problem

Exclusion criteria:

Any allergy to lavender

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize and assign people to the intervention and control groups, the function of random numbers will be used, so that in the Excel software, the groups are first entered in the form of A and B below each other in one column; Because the number of samples in each group is set to 40, therefore, 40, B and A should be entered below each other and in order. In the opposite column, random numbers are generated using the RAND command. In the next step, using the sort command, the generated random numbers are sorted from small to large or vice versa, which changes the order of the groups, A, B. Using the new order, people are assigned to different groups

Blinding (investigator's opinion)

Single blinded

Blinding description

Both the control and observation groups do not know the type of scent that is used, and instead of writing the name on the bottle of solution used, the number one and two is written. The researcher is aware of this numbering. The solutions are used in a closed glass bottle that is the same in terms of color and volume of the solution. Also, in order to carry out the intervention, the control and intervention groups are in separate rooms.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in research of pharmacy, nursing and midwifery faculties - Shahid Beheshti Universi

Street address

No. 135, Helal Ahmar9 Ave., nehzat Blv

City

Semnan

Province

Semnan

Postal code

3514864441

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.228

Health conditions studied

1

Description of health condition studied

آندوسکوپی دستگاه گوارش

ICD-10 code

K83.1

ICD-10 code description

Obstruction of bile duct

Primary outcomes

1

Description

satisfaction

Timepoint

Before and after the intervention

Method of measurement

Satisfaction questionnaire

2

Description

Pain

Timepoint

Before and after the intervention

Method of measurement
Pain Visual Numerical Questionnaire

3

Description
Physiological index
Timepoint
Before and after the intervention
Method of measurement
دستگاه پالس اکسی متری

Secondary outcomes

1

Description
Allergy to lavender
Timepoint
After intervention for 3 days
Method of measurement
Examining side effects caused by medication by asking the patient

Intervention groups

1

Description
Before the endoscopy, four drops of lavender essential oil with a concentration of 2% (product of Zardband company) will be dripped on sterile gauze and placed on the chest of patients in the intervention group, and they will be asked to inhale it for 30 minutes.
Category
Treatment - Drugs

2

Description
Control group: Before the endoscopy, four drops of normal saline are dripped on sterile gauze and placed on the chest of control group patients, and they will be asked to inhale it for 30 minutes.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Roya Rajabi
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No. 135, Helal Ahmar9 Ave., nehzat Blv
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ismaili
Street address
No. 135, Helal Ahmar9 Ave., nehzat Blv
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roya Rajabi
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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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
Based on the objectives in the proposal, the level of satisfaction, pain and physiological index before and after aromatherapy are reported and some individual information mentioned in the variable section.
When the data will become available and for how long
November 1401
To whom data/document is available
Researchers, Shahid Beheshti University of Medical Sciences, study subjects, university and hospital researchers
Under which criteria data/document could be used
After analysis, the data are available to others through publication in scientific research journals.
From where data/document is obtainable
Roya rajabi .E-mail: rajabiroya00@sbmu.ac.ir. phone number 09123313745. No 135., Helal Ahmar9 Ave., Nehzat Blv
What processes are involved for a request to access data/document
Information will be available through printing the article. But if a person wants more and additional information, he can express his request through email, phone and in person. Then, according to the amount and type of data that will be considered, information is provided.
Comments