

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Street address

No. 135, Helal Ahmar9 Ave., nehzat Blv

City

Semnan

Province

Semnan

Postal code

3514864441

Phone

+98 23 3344 4329

Email

rajabiroya00@sbmu.ac.ir

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

City

Semnan

Province

Semnan

Postal code

3514864441

Phone

+98 912 331 3745

Email

rajabiroya00@sbmu.ac.ir

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

Street address

No. 135, Helal Ahmar9 Ave., nehzat Blv

City
Semnan
Province
Semnan
Postal code
3514864441
Phone
+98 23 3344 4329
Email
rajabiroya00@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roya Rajabi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 135, Helal Ahmar9 Ave., nehzat Blv
City
Semnan
Province
Semnan
Postal code
3514864441
Phone
+98 23 3344 4329
Email
rajabiroya00@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Rajabi Roya
Position
Masret Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 135, Helal Ahmar9 Ave., nehzat Blv

City
Semnan
Province
Semnan
Postal code
3514864441
Phone
+98 23 3344 4329
Email
rajabiroya00@sbmu.ac.ir

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