

# 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

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#### 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

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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 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**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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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