

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the effect of deep breathing with and without rosemary on pain, sleep quality and hemodynamic indicators during and after upper limb orthopedic surgery

#### Protocol summary

##### Study aim

Determining the effect of deep breathing with and without rosemary on pain, sleep quality and hemodynamic indicators during and after orthopedic surgery of the upper limb in reference to 17 Shahrivar Amol Hospital in 2023

##### Design

It is a three-arm parallel randomized clinical trial with a sample size of 102 people in a continuous, accessible and random allocation manner.

##### Settings and conduct

In the hospital on 17th Shahrivar Amol, the breathing group with and without rosemary will perform deep breathing 12 times in the morning and 12 times in the evening for 7 days. The insert envelope and the type of intervention or control are specified inside the envelope.

##### Participants/Inclusion and exclusion criteria

Admission: over 18 years old, ability to read and write and communicate in Persian language; presence of any fractures and tears in the upper limbs (surgery time 30 minutes to 3 hours); full alertness; not suffering from respiratory diseases such as asthma, bronchitis and emphysema, not smoking; no pregnancy and breastfeeding; no allergy to rosemary; ASA1 and ASA2 anesthesia class one and two. Withdrawal: refusal to continue the study; creating an unwanted cardio-respiratory complication during anesthesia and surgery; suffering from compartment syndrome.

##### Intervention groups

Breathing group with rosemary while the necklace containing rosemary essential oil is poured on cotton and placed at a distance of 20 cm from the person's nose, deep breathing is done lying down and sitting. The deep breathing group without rosemary is similar to deep breathing with rosemary and only from Normal saline will be used and routine procedures will be performed and recorded in the control group

#### Main outcome variables

Pain at the operation site; pain at the tourniquet site; sleep quality; hemodynamic indices; awareness and recall of events during anesthesia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230209057374N1**

Registration date: **2023-04-13, 1402/01/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-13, 1402/01/24**

Update count: **0**

##### Registration date

2023-04-13, 1402/01/24

##### Registrant information

##### Name

Bahare Rozgard

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4415 5676

##### Email address

bahare.rozgard@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-07-20, 1402/04/29

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of deep breathing with and without rosemary on pain, sleep quality and hemodynamic indicators during and after upper limb orthopedic surgery

**Public title**  
Comparison of the effect of deep breathing with and without rosemary on pain, sleep quality and hemodynamic indicators in upper limb orthopedic surgery.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Over 18 years of age The ability to read and write and communicate in Persian The presence of any fractures and tears in the upper limbs (which will take approximately 30 minutes to 3 hours for surgery) Being fully alert Not suffering from any disease have respiratory problems such as asthma, bronchitis and emphysema Not smoking Not pregnant or breastfeeding Not allergic to rosemary Class one and two anesthesia ASA1 and ASA2

**Exclusion criteria:**

Discontinuing the study Unwanted cardiovascular and respiratory complications during anesthesia and surgery Suffering from compartment syndrome

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **102**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For this research, before the start of the study, after obtaining informed consent before the operation, the patients are referred continuously and available, and with the block randomization method, they are divided into three groups: deep breathing without rosemary (B), deep breathing with rosemary (R). , control (C) or routine will be assigned. The blocks of this study are 6 (BB, RR, CC) and 27 states will be created, first determine the possible states of these 6 letters inside the blocks and then randomly and using the table of random numbers

number 17 from the block. which will be the completion of the number of samples will be determined (1-27) and in this way the type of intervention will be determined based on the desired letters with the number of each patient and will be kept in a master sheet and the continuous entry number of the patients will be inserted on the envelope respectively And the type of intervention or control is specified inside the envelope. Gradually, according to the presence of eligible patients, the relevant envelope is returned, and the type of intervention that is inside the non-transparent envelope is determined and the desired technique is performed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to blind the patients, the same cotton necklace is used for all patients, although the cotton impregnated with rosemary essential oil contains perfume, an effort is made to ensure that there is no communication between the patients during the study period. And to blind the researchers, the opening of the envelope was done by the secretary of the department, who has no role in the evaluation of the groups, and the person who measures the variables is not aware of the type of intervention. Considering the different forms of providing services to the study groups, the behaviors in dealing with the three groups are tried to be similar in terms of having a cotton necklace dipped in rosemary oil or normal saline and without these items. However, it is not possible to completely blind due to the smell of rosemary.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

**Street address**

Journal Office - Research and Technology Deputy - Third Floor - Building No. 2, Mazandaran University of Medical Sciences and Healthcare Services - Moalem Square - Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

1295498972

**Approval date**

2023-01-16, 1401/10/26

**Ethics committee reference number**

sweating, tachycardia, and increased blood pressure in response to painful stimulation (skin incision)

## Health conditions studied

### 1

#### **Description of health condition studied**

Any tear or fracture in the upper limbs

#### **ICD-10 code**

XIII

#### **ICD-10 code description**

Diseases of the musculoskeletal system and connective tissue

## Primary outcomes

### 1

#### **Description**

Pain score

#### **Timepoint**

Recording the pain score of the operation site at the time of discharge from recovery and 24 hours, 48 hours, 4 days and 7 days after surgery

#### **Method of measurement**

Visual Analog Scale

### 2

#### **Description**

Tourniquet site pain score

#### **Timepoint**

Discharge from recovery and 24 hours after the operation

#### **Method of measurement**

Visual Analog Scale

### 3

#### **Description**

Evaluation of sleep quality

#### **Timepoint**

Evaluation of sleep quality the night before and the first night after surgery, as well as 48 hours, 4 days and 7 days after surgery.

#### **Method of measurement**

Pittsburgh Sleep Quality Questionnaire

### 4

#### **Description**

Examining waking up during anesthesia, symptoms include: dizziness, rapid meiosis in response to light, tears, targeted movements of facial muscles and limbs, sweating, tachycardia, and increased blood pressure in response to painful stimulation (skin incision)

#### **Timepoint**

The beginning of surgery (skin incision) and the end of surgery (skin suture)

#### **Method of measurement**

Dizziness, rapid meiosis in response to light, tears, targeted movements of facial muscles and limbs,

### 5

#### **Description**

Examining recall of events during anesthesia with questions: hearing the sounds during the operation, feeling the stretch of the viscera and feeling the pain

#### **Timepoint**

In 24 hours and 7 days after anesthesia

#### **Method of measurement**

Hearing the sounds during the operation, feeling the stretch of the viscera and feeling the pain

### 6

#### **Description**

Registration of hemodynamic indicators including: systolic and diastolic blood pressure, heart rate and arterial blood oxygen

#### **Timepoint**

Entering the operating room, during the operation and at the time of discharge from recovery

#### **Method of measurement**

Monitoring device

## Secondary outcomes

empty

## Intervention groups

### 1

#### **Description**

The first intervention group: Deep breathing with rosemary while the necklace containing three drops of 4% rosemary essential oil from the essential plant company is poured on cotton and is placed at a distance of 20 cm from the person's nose and the person inhales its aroma, at first there are explanations about Breathing skills, deep breathing and its effects on physical and mental health are given, then deep breathing training is first done lying down and then sitting up, before the surgery with the help of educational notes and the researcher's guidance by the patients, so that in terms of learning and the correct execution of the technique will be controlled and this training will be face-to-face. On the first day, they will do this exercise 12 times at the beginning of the day and 12 times in the evening before dinner, for 15 minutes. To perform abdominal breathing, the patient is taught to lie on his back on the floor and to bend his legs slightly apart from the hip width so that the lower back rests comfortably on the floor. Place the healthy hand on your stomach. Take a slow and deep breath through the nose while slowly expanding the abdominal muscles up and to the side and the belly expands, hold your breath for 5 seconds and then exhale slowly and smoothly through the nose. Exhale all the air from your lungs. The patient looks and pays attention to the abdominal muscles while inhaling and exhaling.

#### **Category**

Treatment - Other

## 2

### Description

The second intervention group: deep breathing without rosemary while the necklace containing normal saline is poured on cotton and placed at a distance of 20 cm from the person's nose and the person inhales it, at first explanations about breathing skills, deep breathing and its effects It is given on physical and mental health, then deep breathing training is first done lying down and then sitting up, before the surgery with the help of educational notes and the guidance of the researcher, the patients will be controlled in terms of learning and doing the technique correctly, and this Training will be face-to-face. On the first day, they will do this exercise 12 times at the beginning of the day and 12 times in the evening before dinner, for 15 minutes. To perform abdominal breathing, the patient is taught to lie on his back on the floor and to bend his legs slightly apart from the hip width so that the lower back rests comfortably on the floor. Place the healthy hand on your stomach. Take a slow and deep breath through the nose while slowly expanding the abdominal muscles up and to the side and the belly expands, hold your breath for 5 seconds and then exhale slowly and smoothly through the nose. Exhale all the air from your lungs. The patient looks and pays attention to the abdominal muscles while inhaling and exhaling.

### Category

Treatment - Other

## 3

### Description

Control group: the routine procedures of the ward and operating room will be performed and recorded, and they will use a cotton necklace without rosemary and normal saline.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

17 Shahrivar Hospital

##### Full name of responsible person

Shahram Kashani

##### Street address

17 Shahrivar Hospital, 17 Shahrivar Square, Amol, Mazandaran

##### City

Amol

##### Province

Mazandaran

##### Postal code

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##### Phone

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##### Email

rayane17sh@live.com

##### Web page address

<http://h-17shahrivar.mazums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Pedram Ebrahimnejad

##### Street address

Sari Research and Technology Vice-Chancellor, 3rd Floor, Moalem Square, Building No. 2, Mazandaran University of Medical Sciences and Healthcare Services

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##### Province

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##### Phone

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##### Email

[jmums@mazums.ac.ir](mailto:jmums@mazums.ac.ir)

##### Web page address

<http://jmums.mazums.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ebrahim Nasiri Formi

##### Position

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

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**Full name of responsible person**

Ebrahim Nasiri Formi

**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available