

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)

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Email address

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

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

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Position

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Latest degree

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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