

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of inhalation of rosemary fragrance on alleviating post orthopedic surgery pain(hip prosthesis placement) in ICU patients

Protocol summary

Study aim

Effects of inhalation of rosemary fragrance on alleviating post orthopedic surgery pain(hip prosthesis placement) in ICU patients

Design

Clinical trial with control group, with parallel group, three-way blind, randomized, phase 3 on 64 patients. For randomization, a table of random numbers has been used,

Settings and conduct

Patients who are candidates for orthopedic surgery (implantation of hip prosthesis) admitted to Imam Hospital. After surgery patients are divided into 2 main groups. Intervention group of gas impregnated with 3% rosemary essential oil and control group of gas soaked in sweet almond oil are attached to their clothes at a distance of 20 cm from their noses. Anesthesia method for both groups in the operating room is general anesthesia with the same drugs. Blinding is performed on patients, evaluators and data analysts in 3 directions.

Participants/Inclusion and exclusion criteria

Admission requirements: Patients aged 18-70 years with ASA class III maximum candidate for at least 24 hours stay in ICU after orthopedic surgery and implantation of hip prosthesis. Conditions for not entering the study: Drug dependence, pregnancy and lactation, dissatisfaction, allergy to rosemary any length of surgery or complications during and after surgery and out of the same care, routine user of any analgesic in the period of 2 months before surgery, uncontrolled high blood pressure, Epilepsy.

Intervention groups

In the intervention group: inhalation of gas impregnated with 3% rosemary essential oil is performed. Control group: inhalation of gas soaked in sweet almond oil.

Main outcome variables

Pain before and after intervention in two groups of patients; morphine use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211102052945N1**

Registration date: **2022-05-16, 1401/02/26**

Registration timing: **retrospective**

Last update: **2022-05-16, 1401/02/26**

Update count: **0**

Registration date

2022-05-16, 1401/02/26

Registrant information

Name

Abbas Mohaddes Hakkak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3762 9230

Email address

a.mh95@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of inhalation of rosemary fragrance on alleviating post orthopedic surgery pain(hip prosthesis placement) in ICU patients	
Public title	Effects of inhalation of rosemary fragrance on alleviating pain
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patients aged 18-70 year old ASA class III maximum Candidate for at least 24 hours stay in ICU Post orthopedic surgery and implantation of hip prosthesis Exclusion criteria: Drug addiction Pregnancy and lactation Dissatisfaction Allergy to rosemary Any length of surgery or complications during and after surgery and leaving the same care Routine user of any analgesic in the period of 2 months before surgery Uncontrolled high blood pressure Epilepsy
Age	From 18 years old to 70 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Outcome assessor - Data analyser
Sample size	Target sample size: 64 More than 1 sample in each individual Number of samples in each individual: 9 For all patients upon arrival and every 3 hours
Randomization (investigator's opinion)	Randomized
Randomization description	Table of random numbers using the site: www.randomization.com
Blinding (investigator's opinion)	Triple blinded
Blinding description	The study is a three-way blind study that includes participants, evaluators and data analysts.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	Name of ethics committee Ethics Committee of Mashhad University of Medical Sciences Street address Ghoreishi building, Daneshgah street, Mashhad City Mashhad Province Razavi Khorasan Postal code 9137913316 Approval date 2021-01-19, 1399/10/30 Ethics committee reference number IR.MUMS.MEDICAL.REC.1400.202
Health conditions studied	
1	
Description of health condition studied	Acute pain
ICD-10 code	R52.0
ICD-10 code description	Acute pain, not elsewhere classified
Primary outcomes	
1	
Description	Patients' pain score based on NSR questionnaire
Timepoint	Measure the patient's pain at the time of admission to the ICU and every 3 hours for up to 24 hours
Method of measurement	Numeric Rating Scale questionnaire
Secondary outcomes	
1	
Description	Amount of morphine used
Timepoint	If necessary, once every ten minutes
Method of measurement	Record the prescribed drug by dose
Intervention groups	
1	
Description	Intervention group: All patients undergo anesthesia after pre-medication with 1 mg midazolam and 3 micrograms/kg fentanyl with 2 mg/kg propofol and 0.5 mg/kg atracurium. At the end of the surgery, the patient is admitted to the surgical ICU after extubation and without recovery and receives the same care. For all

patients, at the beginning of admission and every 3 hours, pain determination is performed according to the NRS scoring system and if the score is more than 3, 0.05 mg/kg of intravenous morphine is prescribed every 10 minutes to reduce the pain score to less than 4. In addition to these treatments, in the intervention group, a gauze impregnated with 5 drops of 3% rosemary essential oil (about one cc of essential oil on a 5*5 cm gauze) will be pinned to the patient's shirt and will be renewed every three hours. The score of pain and the required dose of morphine will be recorded every 3 hours for 24 hours.

Category

Treatment - Drugs

2

Description

Control group: All patients undergo anesthesia after pre-medication with 1 mg midazolam and 3 micrograms/kg fentanyl with 2 mg/kg propofol and 0.5 mg/kg atracurium. At the end of the surgery, the patient is admitted to the surgical ICU after extubation and without recovery and receives the same care. For all patients, at the beginning of admission and every 3 hours, pain determination is performed according to the NRS scoring system and if the score is more than 3, 0.05 mg/kg of intravenous morphine is prescribed every 10 minutes to reduce the pain score to less than 4. In addition to these treatments, in the control group, a gauze impregnated with 5 drops of sweet almond oil (about one cc of oil on a 5*5 cm gauze) will be pinned to the patient's shirt and will be renewed every three hours. The score of pain and the required dose of morphine will be recorded every 3 hours for 24 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Arash Peivandi Yazdi

Street address

Department of anesthesia, Imam Reza Hospital, Ibne Sina Street

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peivandia@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Arash Peivandi Yazdi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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