Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Investigating the effect of back massage on pain and hemodynamic variables of patients hospitalized in the intensive care unit.

Protocol summary

Study aim
Determining the effect of back massage on pain and hemodynamic symptoms of in patients in the intensive care unit

Design
Phase III Clinical Trial with Control Group, single-blinded, blocked randomization, on 60 patients

Settings and conduct
The population included patients hospitalized in the intensive care unit of four educational hospitals affiliated to Kermanshah University of Medical Sciences (Emam Reza, Imam Khomeini, Ayatollah Taleghani, and Farabi hospitals). Before the intervention, the pain variable is measured using the Critical-Care Pain Observation Tool, and blood pressure, heart rate, respiratory rate, and oxygen saturation level are measured using a monitor. Intervention is performed for one time for 15 minutes and at the end pain variable and hemodynamic variables are measured again. This study will be single-blind, and the statistical analyst and the researcher who performs random allocation are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Consent of the Patient's legal Guardian for Cooperation 2. Patients with Glasgow Coma Scale (GCS) less than 8 3. Hospitalization History of more than 48 Hours in the Intensive Care Unit 4. Age between 18 and 70 Years Exclusion criteria: 1. Prohibition of Changing Body Position for the Patient 2. Severe Head Injury 3. Skin Wounds in the Massage Area 4. Previous Operations in the Back, lung and Abdomen

Intervention groups
In the intervention group, each back massage session includes a combination of Effleurage, Petrissage, Friction, and Tapotement techniques for 15 minutes (between 16:00 and 18:00) in the lumbar region, back, shoulder blades, shoulders and it is applied to the neck area. There is no intervention in the control group.

Main outcome variables
The primary outcome of the plan is changes in pain, and changes in pain intensity can cause changes in hemodynamic variables as a secondary outcome.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231010059680N1**
Registration date: **2023-12-19, 1402/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-19, 1402/09/28**
Update count: **0**

Registration date
2023-12-19, 1402/09/28

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-16, 1402/09/25

Expected recruitment end date
2024-01-15, 1402/10/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of back massage on pain and hemodynamic variables of patients hospitalized in the intensive care unit.

Public title
Investigating the effect of back massage on pain and hemodynamic variables of patients hospitalized in the intensive care unit

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Consent of the Patient's legal Guardian for Cooperation Patients with Glasgow Coma Scale (GCS) less than 8 Hospitalization History of more than 48 Hours in the Intensive Care Unit Age between 18 and 70 Years
Exclusion criteria:
Prohibition of Changing Body Position for the Patient Severe Head Injury Skin Wounds in the Massage Area Previous Operations in the Back, lung and Abdomen

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
First, the required number is selected from among the people who meet the inclusion criteria, and then these selected people are assigned to each of the intervention and control groups. The best method of allocating the studied subjects to each of the intervention and control groups is random allocation which can be implemented in different ways. The first step towards implementing a random process is creating random sequences. In this study, the creation of random sequences is done by a finite randomization method called block randomization to balance the number of samples allocated to each of the studied groups. This method consists of a large block for the total sample size in which the block is selected by selecting blocks with the size of each block of four (2 participants in the intervention group and 2 participants in the control group) and each of the six possible states of the number for the block of four is assigned as follows: 1) AABB 2) ABAB 3) ABBA 4) BBAA 5) BABA 6) BAAB Using the random table of numbers, the numbers between 1 and 6 are selected and according to each number of the allocation list, intervention or control group will be determined. Sampling will continue until the samples are completed. The second step after random sequence creation is sequence closing, which is called random allocation closing. In this study, the central randomization method is used. In this method, random sequencing is available to a specific person or center, and sampling is done in one or more centers simultaneously. The researcher communicates with the relevant center based on the order of the participants entering the study and asks about the random allocation of the participants to the specific group. The method of communication includes the use of telephone, SMS, email, etc. One of the applications of this method is in multi-center studies. The third step is the random allocation process, which should separate the person responsible for the random program from other researchers (except the person involved in the registration stage of the participants or the assignment of participants to study groups) to minimize the selection bias as much as possible.

Blinding (investigator's opinion)
Single blinded

Blinding description
One of the goals of blinding will be to reduce implementation bias and analysis bias. For this reason, the questionnaires will be completed before assigning the participants to the intervention and control groups, using sealed envelopes (blinding the participants) and presenting the intervention at a time other than the time of presenting the routine programs and presenting the questionnaire to the intervention group. It will be on a day other than the day of presentation to the control group. After the intervention, the people who collected the questionnaires and entered the data were not aware of the group of people, and the data analyst was not from the group of people providing the intervention (blinding of information and analysis). This study will be single blind. This means that the patients are aware of the type of intervention, but the statistical analyst and the researcher who performs the random assignment are blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

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University of Medical Science, Office Building No. 2, Hafezieh District, Kermanshah

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Approval date

2023-10-10, 1402/07/18

Ethics committee reference number

IR.KUMS.REC.1402.296

Health conditions studied

1

Description of health condition studied

The effect of back massage on pain and hemodynamic symptoms of in patients in the intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in Critical Care Pain Observation Tool

Timepoint

Immediately after the end of the intervention

Method of measurement

Critical Care Pain Observation Tool is a tool used to measure pain in patients who are unable to verbally describe their pain. This tool consists of four parts. 1- facial expression, 2- body movements, 3- muscle stiffness, and 4- patient adaptation to ventilator in intubated patients. Each step is scored between 0 and 2 points according to the patient's condition. The maximum score is eight, which indicates excessive pain, and the absence of pain is scored as zero.

Secondary outcomes

1

Description

Changes in blood pressure

Timepoint

Immediately after the end of the intervention

Method of measurement

Patient vital signs monitor device

2

Description

Change in heart rate

Timepoint

Immediately after the end of the intervention

Method of measurement

Patient vital signs monitor device

3

Description

Change in respiratory rate

Timepoint

Immediately after the end of the intervention

Method of measurement

Patient vital signs monitor device

4

Description

Change in oxygen saturation level

Timepoint

Immediately after the end of the intervention

Method of measurement

Patient vital signs monitor device

Intervention groups

1

Description

Intervention group: All patients who meet the inclusion criteria in the intervention group are placed in the right-side lying position because gas exchange and pulmonary perfusion are better in this position. According to the study protocol of Yilmaz et al (2020), before the massage, the patients and their environment are prepared, and privacy is ensured. A drop of liquid Vaseline smears at room temperature. Liquid Vaseline is used to lubricate the skin and reduce friction. Each back massage session includes a combination of Effleurage, Petrissage, Friction, and Tapotement techniques. The back massage begins with the exfoliation movement (gliding), and then we lift and knead the skin, subcutaneous tissue, and muscles with our fingers (Petrissage). In the next step, using fingers and thumb, we take the subcutaneous tissue and muscle and move from the hip area to the shoulder. Then, in the area of the cervical spine, we apply gentle pressure around each vertebra with small circular movements (Friction), then use the outer edge of the hand to rhythmically hit the soft tissue structures (Tapotement). The massage continues for 15 minutes and ends with the Effleurage technique. Back massage is applied to the lumbar region, back, shoulder blades, shoulders, and neck area. In the intervention group, before the intervention, the pain is measured using the Critical Care Pain Observation Tool (CPOT) for measuring the pain of special care patients, and blood pressure, heart rate, breathing rate, and oxygen saturation level are measured using the monitor system of each patient. The intervention is performed once (between 16:00 and 18:00) for 15 minutes, and at the end, two variables of pain and hemodynamic variables are measured again.

Category

Rehabilitation

2

Description

Control group: In the control group, the pain variable is measured using the Critical Care Pain Observation Tool (CPOT), and the blood pressure, heart rate, breathing rate, and oxygen saturation level are measured using the monitor system of each patient, and 15 minutes later

without No re-intervention, all variables are measured and recorded.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Sara Ashrafabadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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