

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of back massage by hand and hot towel on muscle pain and pulmonary function of patients undergoing open-heart surgery

Protocol summary

Study aim

Comparison of the effect of back massage by hand and hot towel on muscle pain and pulmonary function of patients undergoing open-heart surgery in the intensive care unit of selected Aja hospitals

Design

Three-group clinical trial with two intervention groups and one control group, non-blind test and randomized selection

Settings and conduct

This study will be performed on patients undergoing open-heart surgery in the intensive care unit of Shahid Doran Hospital in Shiraz in 2020-2021.

Participants/Inclusion and exclusion criteria

90 patients who met the necessary criteria for inclusion in the study, including satisfaction, not attending similar sessions, not suffering from mental retardation and alertness, and did not use drugs.

Intervention groups

Massage group: The patient will be in a comfortable position, ie sitting slightly bent forward, then stroke massage with dry and clean hands will be applied on the patient's back area on the second, third, and fourth days after the operation and for 20 minutes. Hot towel group: The patient will be in a comfortable position, ie sitting slightly bent forward, then a towel measuring 50×50 cm with a temperature of 42 ° C on the patient's back on the second, third and fourth days after Practice and apply for 20 minutes. Control group: will only receive routine care.

Main outcome variables

Pain intensity, pulmonary function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201203049582N1**

Registration date: **2021-04-21, 1400/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-21, 1400/02/01**

Update count: **0**

Registration date

2021-04-21, 1400/02/01

Registrant information

Name

Marzieh Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8609 6350

Email address

marziyehzare90@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of back massage by hand and hot towel on muscle pain and pulmonary function of patients undergoing open-heart surgery

Public title

Comparison of the effect of back massage by hand and hot towel on muscle pain and pulmonary function

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The satisfaction to participate in the study Do not use massage and hot towels for the previous three months Do not suffer from mental retardation No drug addiction Having full consciousness Ability to communicate verbally and visually

Exclusion criteria:

Bleeding less than 200 cc per hour from the chest tube Presence of a wound or skin disease in the back

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

90 patients will be selected based on the criteria for entering the study and based on the Target-based sampling method and will be randomly assigned to three groups of massage intervention, hot towel intervention, and control (30 people in each group). In this way, patients with code one will be placed in the group of massage intervention, code two with hot towel intervention and code three with control, and will continue until number 90.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the AJA University of Medical Sciences

Street address

Tehran, West Fatemi St, Shahid Etemadzadeh St, AJA University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.AJAUMS.REC.1400.005

Health conditions studied**1****Description of health condition studied**

Cardiovascular Diseases

ICD-10 code

I25.11

ICD-10 code description

Atherosclerotic heart disease of native coronary artery with angina pectoris

Primary outcomes**1****Description**

Pain Intensity

Timepoint

The second, third and fourth days after surgery

Method of measurement

Visual Analog Scale (VAS)

2**Description**

Pulmonary function

Timepoint

The second, third and fourth days after surgery

Method of measurement

Based on the results of incentive spirometry

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The first group (massage therapy intervention): The patients will be in a comfortable position, ie sitting slightly bent forward, then stroke massage with dry and clean hands will be applied on the patient's back area on the second, third and fourth days after the operation and for 20 minutes.

Category

Rehabilitation

2

Description

Intervention group: The second group (hot towel intervention):The patients will be in a comfortable position, ie sitting slightly bent forward, then a towel measuring 50×50 cm with a temperature of 42 ° C on the patient's back on the second, third and fourth days after Practice and apply for 20 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Abbas Dowran Hospital

Full name of responsible person

Marzieh Zare

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zeshk

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Marzieh Zare

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Fatemeh Kalroozi

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Master

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