

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of head and facial massage on sleep condition after Coronary artery bypass graft surgery

Protocol summary

Study aim

Determining of the effect of head and facial massage on sleep condition after Coronary artery bypass graft surgery

Design

72 patients were randomly assigned into two groups of 36 in a randomized massage and control group based on the Permuted Block Randomization computer program.

Settings and conduct

The intervention starts from the third night after the operation and is performed 3 consecutive nights around 19-21 pm head and face massage for the intervention group. In the evening of the third to fifth day after the operation, before the intervention the RCSQ questionnaire for both massage therapy and control groups is completed. The study site is Fatemeh Zahra Hospital in Sari.

Participants/Inclusion and exclusion criteria

The age of adults over 18 years of age, those undergoing coronary artery bypass grafting, their vital signs are stabilized, not needing for intra-aortic pump balloons and intubation for more than 24 hours, no infection or sores on the head and face; Pulmonary drainage and discharge of more than 200 cc per hour, The patient's unwillingness to cooperate during the research, The patient's condition becomes critical and the patient returns to the operating room.

Intervention groups

The intervention begins on the third night after the operation and 3 consecutive nights 2 to 3 hours before bedtime, for the intervention group 15 minutes head and face massage is done and in the control group, no intervention is done.

Main outcome variables

sleep condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110906007494N35**

Registration date: **2021-01-22, 1399/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-22, 1399/11/03**

Update count: **0**

Registration date

2021-01-22, 1399/11/03

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of head and facial massage on sleep condition after Coronary artery bypass graft surgery

Public title

The effect of head and facial massage on sleep condition after Coronary artery bypass graft surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The age of adults over 18 years of age those undergoing coronary artery bypass grafting their vital signs are stabilized (blood pressure, temperature, pulse, respiration) lack of communication problems (hearing, vision or speech impairment) not using drug lack of cognitive problems and delirium not using anti-depressant drugs and antihistamines lack of sleep disorders treated in a recent month lack of severe neuropathy in the patient not needing for intra-aortic pump balloons and intubation for more than 24 hours no infection or sores on the head and face

Exclusion criteria:

Pulmonary drainage and discharge of more than 200 cc per hour The patient's unwillingness to cooperate during the research The patient's condition becomes critical and the patient returns to the operating room The patient's unwillingness to continue working and taking sleeping drugs and antihistamines

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients are divided into two groups of 36 interventions and witnessed by random numbers provided with computer software and Permuted Block Randomization under the guidance of a statistical consultant. 18 blocks of 4 so that in each block there are 2 people from each group. 72 envelopes have been designed in which the letters A (massage therapy group) and B (control group) are embedded according to a computer program, and the envelopes from number one to 72 are prepared on the envelopes. He enters and has the criteria for admission, After obtaining written consent, he enters the study and the sampling continues until patient number 72.

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 Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

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Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2020-12-28, 1399/10/08

Ethics committee reference number

IR.MAZUMS.REC.1399.803

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

sleep condition

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

sleep condition

Timepoint

determination sleep condition at third to fifth day after surgery, before the intervention in control and massage group.

Method of measurement

Richard Campbell Sleep Questionnaire

Secondary outcomes

empty

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

Intervention group: head and facial massage will be done for 15 minutes for every person from third day after surgery started and continued for 3 nights.

Category

Lifestyle

2

Description

Control group: Not done any massage

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital in Sari

Full name of responsible person

Masoomah Rajabi Ozudi

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Juibar three ways, Mazandaran University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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Mazandaran University of Medical Sciences ,valiye asr highway, Joybar 3way ,Imam Sq,Sari, Mazandaran, Iran

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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

Dr.Masoumeh Bagheri Nesami

Position

phd Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available