Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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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Mazandaran
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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
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Sponsors / Funding sources

1

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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

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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