

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of face and head massage on the severity score of delirium after coronary artery bypass graft surgery in patients hospitalized in cardiac surgery intensive care unit.

Protocol summary

Study aim

The effect of face and head massage on delirium severity score after coronary artery bypass graft surgery

Design

This study is a clinical trial in which 104 patients who were candidates for coronary artery bypass graft surgery were examined and randomly divided into experimental and control groups.

Settings and conduct

This study will be performed in Afshar Hospital in Yazd and for patients in the experimental group, facial and head massage therapy will be performed by a trained person according to the patient's gender.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 60 and 75 years; Conscious consent to participate in the study; Lack of delirium; Exit criteria: No dependence on drugs and alcohol; Lack of vision and hearing problems; No history of known cognitive and mental illness; Not receiving drugs that affect the nervous system; Absence of any lesions and skin diseases on the face and head;

Intervention groups

In patients of the experimental group, facial and head massage therapy will be performed based on thirteen Brown massage therapy techniques. Massage therapy will be performed on the third and fourth days of hospitalization in the morning and evening sessions, which are four sessions in total. Each technique is repeated 5 times. The time of each massage therapy session is 15 minutes. Massage therapy will not be performed in patients in the control group and routine measures will be performed to prevent delirium.

Main outcome variables

Abundance of delirium Intensity of delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211223053492N1**

Registration date: **2022-02-08, 1400/11/19**

Registration timing: **retrospective**

Last update: **2022-02-08, 1400/11/19**

Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Ebrahim Sheykhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3283 1135

Email address

e.sheykhi@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of face and head massage on the severity score of delirium after coronary artery bypass graft surgery in patients hospitalized in cardiac surgery intensive care unit.

Public title

The effect of face and head massage on the severity score of delirium after coronary artery bypass graft surgery in patients hospitalized in cardiac surgery intensive care unit.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 to 75 years Conscious consent to participate in the study Lack of delirium

Exclusion criteria:

Dependence on drugs and alcohol Sight and hearing problems History of known cognitive and mental illness Receiving drugs that affect the nervous system Existence of any lesions and skin diseases on the head and face

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a table of random numbers, each patient was numbered. Paired numbers belonging to the experimental group and odd numbers for the control group were considered.

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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bahonar Square

City

yazd

Province

Yazd

Postal code

8931639871

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

ir.ssu.rec.1398.243

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.9

ICD-10 code description

F05.9

Primary outcomes

1

Description

Intensity of delirium and frequency of delirium

Timepoint

The first day of hospitalization, the third and fourth day of hospitalization

Method of measurement

Nicham Confusion Assessment Form

Secondary outcomes

1

Description

intensity of delirium

Timepoint

The third and fourth day of hospitalization twice a day at 10 and 18 o'clock

Method of measurement

Brown massage therapy technique

Intervention groups

1

Description

Experimental group: In this group, facial and head massage therapy according to Brown massage therapy techniques, which includes thirteen techniques, will be performed on the third and fourth days of hospitalization in the morning and evening. The duration of each massage is 15 minutes. Each time the massage is repeated 5 times.

Category

Prevention

2

Description

Control group:Control group: In this group, routine measures will be performed to prevent delirium. Massage therapy will not be performed in this group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshari Hospital

Full name of responsible person

Ebrahim Sheikhi Abarqoui

Street address

jomhory Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Hoshang Mehrparvar

Street address

Bahonar Square, the central building of Yazd Shahid Sadoughi University of Medical Sciences

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Ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Ebrahim Sheikhi Abarqoui

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

Contact

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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