Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
City
yazd
Province
Yazd
Postal code
8931639871
Phone
+98 35 3525 5011
Email
e.sheykhi1364@gmail.com

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
City
yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3724 0171
Email
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
Nursery
Street address
Republic Boulevard
City
yazd
Province
Yazd
Postal code
8931639871
Phone
+98 35 3283 1135
Email
e.sheykhi1364@gmail.com

Person responsible for scientific 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
Nursery
Street address
Republic Boulevard
City
yazd
Province
Yazd
Postal code
8931639871
Phone
+98 35 3283 1135
Email
e.sheykhi1364@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Ebrahim Sheikhi Abarqoui

Position
Masters student

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Bachelor

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Nursery

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yazd

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Yazd

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8931639871

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e.sheykhi1364@gmail.com

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