Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of massage with or without aromatic substance on the incidence of delirium in patient undergoing heart surgery in Afshar Hospital, Yazd, in 2017

Protocol summary

Study aim

Applied Research Objectives: Considering the relatively high prevalence of delirium after cardiac surgery, as well as its negative effects on the quality of life of patients, as well as increasing the length of hospitalization and mortality of patients from the disease, the findings of this study may be able to reduce the amount of Delirium treatment after open heart surgery. In addition, given the limited nursing research in this area, this study could clarify the dimensions of the use of complementary medicine and provide a basis for further research in this area.

Design

The study consisted of three groups: one control group and two intervention groups that referred to the patients referred to Afshar Hospital in Yazd for the purpose of open heart surgery, ranging in age from 18 to 75 years, and for the first time Heart surgery. Sampling method is a random allocation.

Settings and conduct

Interventional study - Afshar Hospital in Yazd

Participants/Inclusion and exclusion criteria

Patients entering the study should undergo cardiac surgery for the first time and be between 18 and 75 years of age. Do not mention dermatological sensitivities and their negative sensitivity tests and positive olfactory tests without a history of mental illness or psychiatric use

Intervention groups

Massage with aromatic substance (In this group, 13 brown massage techniques are performed using Rose Essential Oil on the base of sweet almond oil. Then, using a neecham questionnaire, the amount of delirium is measured) Massage without aromatic substance (In this group, 13 brown massage techniques are performed solely by sweet almond oil, then using the neecham questionnaire, the amount of delirium is measured) Control(In this group, Delirium is measured with the neecham questionnaire without massaging.

Main outcome variables

Decreasing the amount of delirium after open heart surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180509039592N1**
Registration date: **2018-06-06, 1397/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-06, 1397/03/16**
Update count: **0**

Registration date

2018-06-06, 1397/03/16

Registrant information

Name

Farzaneh Askarkafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3530 0773

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of massage with or without aromatic substance on the incidence of delirium in patient undergoing heart surgery in Afshar Hospital, Yazd, in 2017

Public title

The effect of massage with or without aromatic substance on the incidence of delirium in patient undergoing heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing cardiac surgery for the first time Age between 18 and 75 years Patients who have a positive olfactory test Patients who have tested negative for their sensitivity Patients who do not mention any history of skin sensitivity Patients who do not mention any history of mental illness or psychiatric use, with the exception of chlordiaspoxide and oxazepam

Exclusion criteria:

If the patient undergoes surgical complications, he or she will be transferred to the operating room. If the patient does not remove the mechanical ventilation until the day after surgery (do not extube) In the event of unwanted and unpredictable effects

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who have inclusion criteria are included in the study using available sampling method and then divided into two intervention and control groups using stratified random allocation method. The samples will be placed in two groups according to gender, age (2 ±), and type of disease. In other words, the first one randomly (using a lottery) is placed in one of the two groups of intervention or control group and the subsequent samples are allocated to each of the groups according to the matching variables and observing random conditions.

Blinding (investigator's opinion)

Single blinded

Blinding description

The therapeutic effect of the intervention has been obscured by participants

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Kerman University of Medical Sciences

Street address

Four Way Somayeh (Tahmasebabad), Beginning of Jihad Boulevard, Beginning of Ibn Sina St

City

kerman

Province

Kerman

Postal code

7619813160

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.KMU.REC.1396.2227

Health conditions studied

1

Description of health condition studied

Delirium after heart surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Delirium: In Delirium DSM-5, Delirium is defined as a distraction of attention and concentration, which usually has a sudden onset, accompanied by disturbance in navigation, short-term memory impairment, change in sensory perception (illusion), abnormal thinking process, and turbulent behavior.

Timepoint

Before the intervention, at the end of each day, until the patient is admitted to the ICU

Method of measurement

NEECHAM delirium measurement questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Massage group with aromatic substance: In this group, samples are received in addition to receiving routine care, massage with scented face and face twice a day (morning and night) until the patient is admitted to the intensive care unit. (Patients are often admitted to the heart care unit for 3 to 4 days). The first massage is the day after the heart surgery, provided that the patient is extubated. The essence of the scent is the Rose Essence. In this study, the essential oil of Rose (produced by Barij Essen, Kashan) is used in the base of sweet almond oil at a concentration of 4%. For each massage, 2 cc of scented oil is used. Prior to initiating the first massage and after massage by another trained person, the incidence and severity of delirium by using the NeeCham questionnaire at the end of each day until the patient is admitted to the intensive care unit and assessed prior to discharge from the caregiver department.

Category

Prevention

2

Description

Intervention group: Massage without aromatic substant: In this group, in addition to receiving routine care, massage with 2 cc sweet peas and almond oil for 15 minutes on the day after the procedure twice a day (morning and night) As long as they are admitted to the intensive care unit. Prior to initiating the first massage and after massage by another trained person, the incidence and severity of delirium by using the NeeCham questionnaire at the end of each day until the patient is admitted to the intensive care unit and assessed prior to discharge from the caregiver department.

Category

Prevention

3

Description

Control group: In the control group only routine care is provided in the heart care unit. In this section, if the illness affects delirium, a psychiatric consultation is requested by the surgeon of the heart and after the visit by the psychiatrist, the medication orders are administered, and the patient's family is asked to come to the patient's appointment in each shift. Connect with him. At the end of each day, until the patient is admitted to the intensive care unit, she is evaluated prior to discharge from the caregiver department

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Afshar Hospital in Yazd

Full name of responsible person
farzaneh askarkafi

Street address
Islamic Republic Boulevard, Afshar Hospital, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr. Abbas Pardakhti

Street address
At the beginning of the axis of haft bagh alavi University of Medical Sciences

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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
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Farzaneh Askarkafi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Potential data can be shared after unidentifiable individuals

When the data will become available and for how long
Start the month access period after printing the results

To whom data/document is available
Researchers working in academia and academia

Under which criteria data/document could be used
The data is sent through an official request and by e-mail

From where data/document is obtainable
f_askarkafi@kmu.ac.ir

What processes are involved for a request to access data/document
The data is sent through an official request and by e-mail

Comments