Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of sensory modification on delirium incidence and cognitive status in open heart surgery intensive care unit's patients

Protocol summary

Summary

This controlled clinical trial study will conduct to determine the effectiveness of sensory modification on delirium incidence and cognitive status in patients of open heart surgery intensive care unit at Amiralmomenin Medical and Educational Center in Kordkuy city in 2015. 120 eligible patients undergoing CABG will be selected via convenience sampling, and then patients will be allocated into two intervention and control groups by using stratified random allocation. Patients in both groups will receive routine nursing care. Furthermore, in intervention group multidimensional intervention for sensory modification will be done including the use of blindfold and earplugs from 12 at night to 6 in the next morning from two to five days after surgery. In addition, family members will visit their patient daily (from 18 to 18:30) to touch and talk them and to orient them to time, place, and person. In both groups delirium incidence will be determined using the Neacham scale and cognitive status will be assessed using the MMSE checklist. Before intervention and 4 consecutive days after intervention (from 2 to 5 days after operation) cognitive status and incidence of delirium will be assessed by trained nurses once in each shift. The data will be analyzed in SPSS-16 software using descriptive, χ2 and Kruskal–Wallis tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121517237N6**
Registration date: **2015-10-29, 1394/08/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-29, 1394/08/07

Registrant information

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Mahnaz Modanloo
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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Golestan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of sensory modification on delirium incidence and cognitive status in open heart surgery intensive care unit's patients

Public title

The effects of sensory modification on delirium incidence and cognitive status in open heart surgery intensive care unit's patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age between 18 and 65 years old 2. The lack of known visual disturbances 3. The lack of known hearing impairment 4. Absence of known psychiatric disorders 5. The lack of known motor disorders in limbs 6. Lack of delirium at baseline 7. Without preoperative cognitive impairment Exclusion criteria: 1. Patients who will be discharged or died during the study 2. The need for CPR during study 3. Patients dissuade for continuing to work with researchers 4. The need for re-operation

Age
From **17 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization strategies: Considering age and gender, patients will be allocated into two intervention and control groups. Allocation will be achieved using stratified random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Golestan University of Medical Sciences

Street address
Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard, Gorgan

City
Gorgan

Postal code
4934174515

Approval date
2015-08-02, 1394/05/11

Ethics committee reference number
ir.goums.rec.1394.86

Health conditions studied

1

Description of health condition studied
Delirium

ICD-10 code
F05.8

ICD-10 code description
Other delirium (Postoperative delirium)

Primary outcomes

1

Description
Delirium

Timepoint
Before and two days after intervention

Method of measurement
Using the NeaCham scale

Secondary outcomes

1

Description
Cognitive status

Timepoint
From two to five days after operation

Method of measurement
By using the MMSE instrument

Intervention groups

1

Description
Intervention group: In addition to routine care, multidimensional intervention for sensory modification will be done including the use of blindfold (made of black cloth), earplugs (Mark Elvex Quattro four-step model, lace) from 12 at night to 6 in the next morning from two to five days after surgery. In addition, family members will visit their patient daily (from 18 to 18:30) to touch and talk them and to orient them to time, place, and person.

Category
Prevention

2

Description
Control group: without any intervention.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Medical & Educational Center

Full name of responsible person
Gholam Ali Riahi

Street address
Amiralmomenin Medical & Educational Center, Mirza Kochak Khan street, Kordkuy

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Kordkuy

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Golestan University of Medical Sciences

Full name of responsible person
Masood KhoshNia

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Deputy of Research and Technology, Golestan University of Medical Sciences (Falsafi Complex), Hirkan Boulevard, Gorgan Gorgan

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Gorgan

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Vice Chancellor for research of Golestan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Golestan University of Medical Sciences

Full name of responsible person
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Position
MS Student of Critical Nursing Care

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty