Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of nursing interventions on the incidence of delirium after open heart surgery

Protocol summary

Study aim
The effect of nursing interventions on the incidence of delirium after open heart surgery

Design
In this study, 60 patients were conveniently sampled and randomly allocated to the experimental and control groups. The random number table will be used for random allocation. Blinding will not be performed in this study. The CAM-ICU scale will be used for diagnosis of delirium.

Settings and conduct
This study will be conducted in the intensive care unit of Shahid Beheshti Hospital in Qom. Interventions will begin immediately after open heart surgery.The intervention will last for three days. Blinding will not be performed in this study. The incidence of delirium in the second and third days after surgery will be compared between the experimental and control groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria: age over 18 years, being a candidate for Coronary Artery Bypass Graft and being alert at the time of admission (Orientation to time, place, and persons). The non-inclusion criteria: being admitted due to emergency heart surgery, isolation due to infectious disease, deterioration of the patient's condition after surgery, having a history of previous major surgery, and a lack of consent.

Intervention groups
In the intervention group, in addition to routine interventions, patients will receive a video tutorial, and Hospital Elder Life Program (HELP). In the control group, only routine care, including walking once a day in the second and third day of surgery, avoiding dehydration, reminding patients of the use of own glasses and hearing aids will be performed.

Main outcome variables
The main outcome variable in this study would be the incidence of delirium.

General information

Reason for update
Incorrect recording of inclusion and exclusion criteria

Acronym

IRCT registration information
IRCT registration number: **IRCT20150724023314N2**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **retrospective**

Last update: **2020-03-02, 1398/12/12**
Update count: **1**

Registration date
2020-02-08, 1398/11/19

Registrant information

Name
Mohammad Abbasinia
Name of organization / entity
Qom university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-01, 1398/06/10

Expected recruitment end date
2019-12-30, 1398/10/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of nursing interventions on the incidence of delirium after open heart surgery

Public title
The effect of a nursing intervention on the incidence of delirium

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age18 years and over being candidate for Coronary Artery Bypass Graft being alert at the time of admission (Orientation to time, place, and persons).

Exclusion criteria:
Being admitted due to emergency heart surgery Isolation due to infectious disease Deterioration of the patient's condition after surgery

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned to intervention and control groups using a random number table.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants were blinded to whether they had been assigned to the intervention or control group throughout the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Qom University of Medical Sciences, Saheli street, Qom.

City
Qom

Province
Ghoum

Postal code
3713649373

Approval date
2019-07-13, 1398/04/22

Ethics committee reference number
MUQ.REC.1398.136

Health conditions studied

1

Description of health condition studied
Delirium

ICD-10 code
F05

ICD-10 code description
Delirium, not induced by alcohol and other psychoactive substances

Primary outcomes

1

Description
Incidence of delirium

Timepoint
First, second and third day of surgery

Method of measurement
CAM-ICU Scale

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, in addition to routine interventions, patients will receive a video tutorial, and Hospital Elder Life Program (HELP).

Category
Prevention

2

Description
In the control group, only routine care, including walking once a day in the second and third day of surgery, avoiding dehydration, reminding patients of the use of own glasses and hearing aids will be performed.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital of Qom

Full name of responsible person
Mohammad Abbasinia

Street address
Shahid Beheshti Hospital, Shahid Beheshti Boulevard, Qom

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Qom

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Ghoum

Postal code
3719964797

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Email
armak1364@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Mohammad Hosori

Street address
No. 83, University of Jihad Alley, Safashahr Street, Qom

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Ghoum

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hozori@muq.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
Mohammad Abbasinia

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable