Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the effect of environmental simulation on the incidence of delirium after coronary artery bypass graft surgery

Protocol summary

Summary

This study aims to assess the effect of environmental simulation on the incidence of delirium in patients undergoing coronary artery bypass graft (CABG) surgery. The study is a clinical trial with control group. The main inclusion criteria are being candidate for CABG and gaining the score of 25 or higher in MMSE test. The main exclusion criteria are a patient decision to withdraw from the study and occurrence of any condition needing special treatment. The patients are randomly allocated into the two groups of 50. The groups are not blinded to the intervention. Before the surgery, both groups are assessed using the MMSE questionnaire. Patients with a MMSE score of 25 or more will be recruited. Patients in the intervention group and one of their main attendances will be interviewed to gather information about the patient's personal affect, interests, emotions and personal items. On the day of surgery, the patient's room and bed will be arranged by his/her personal belongings. After transferring the patient from operation room to the ICU (after consciousness and before tracheal extubation), the patient’s companion will be present at him/her bedside. Three to 4 hours after extubation, the MMSE test will be completed for patients. Moreover, this test will be repeated twice a day (i.e. in the morning and evening) until the patient is discharged from the ICU. The control group will only receive the routine care of the ICU but the MMSE questionnaire will be completed for them at times similar to the intervention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050122029N1**
Registration date: **2017-05-30, 1396/03/09**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-05-30, 1396/03/09

Registrant information

Name

Seiyed Morteza Ghappani

Name of organization / entity

Kashan University of Medical Sciences

Country

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+98 31 5554 0021

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences, Deputy of Research and Technology.

Expected recruitment start date

2015-04-05, 1394/01/16

Expected recruitment end date

2015-09-16, 1394/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of environmental simulation on the incidence of delirium after coronary artery bypass graft surgery

Public title

The effect of environmental simulation on the incidence of delirium

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Any male or female patient who is a candidate for coronary artery bypass graft surgery; having no history of mental illness or diagnosed dementia; gaining the score of 25 or higher in MMSE test on preoperative day (having no delirium or not being at risk of delirium); having no addiction to opium and psychotropic drugs; being literate. Exclusion criteria: unwillingness of patient to cooperate for any reason; occurrence of myocardial infarction or cerebrovascular accidents; occurrence of coma; any condition that requires special treatment; re-intubation for any reason.
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Kashan University of Medical Sciences
Street address
Qotbe Ravandi Blvd.
City
Kashan
Postal code
Approval date
2015-04-08, 1394/01/19
Ethics committee reference number
KAUMS.REC.1394.003

Health conditions studied

1

Description of health condition studied
Coronary artery bypass grafting
ICD-10 code
I21
ICD-10 code description
Acute myocardial infarction

Primary outcomes

1

Description
Delirium
Timepoint
After extubation and twice a day until discharging from ICU
Method of measurement
Mini Mental Status Examination (MMSE)

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group: After using the MMSE test to rule out the delirium, the patients and one of their main companions will be interviewed to gather the information about the patients personal interests, personal belongings and emotional dependence to other family members. Then, patients’ personal belongings such as blanket sheet, spoon, fork and …. as well as favorite belongings such as photo frame, prayer book, Quran or favorite book is received at morning of operation day and after disinfection, they will be arranged in patient’s bedside. After consciousness (during the weaning and before exrtubation), the patient's companion will be presented at the patient's bedside for 10 minutes.
Category
Behavior

2

Description
The control group: This group will receive no intervention other than the routine care of the ICU.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Heart center
Full name of responsible person

Seied Morteza Ghappani
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Qotbe Ravandi Blvd.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Dr Gholam ali Hamidi
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Vice chancellor for research, Kashan University of Medical sciences, Qotbe Ravandi Blv.
City
Kashan
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, Kashan 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
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Imam Ali Heart center
Full name of responsible person
Seied Morteza Ghappani
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Person responsible for scientific inquiries

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Person responsible for updating data

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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