

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

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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 extubation), 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

Street address

Qotbe Ravandi Blvd.

City

Kashan

adib1344@yahoo.co; ghappani-m@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

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

Street address

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

Name of organization / entity

Imam Ali Heart center

Full name of responsible person

Seied Morteza Ghappani

Position

Nursing student

Other areas of specialty/work

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Name of organization / entity

Nursing and Midwifery school

Full name of responsible person

Dr Mohsen Adib-Hajbaghery

Position

Phd of Nursing Education

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Seied Morteza Ghappani

Full name of responsible person

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Position

Nursing graduated

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