Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of family-centered care on the outcomes in patients undergoing coronary artery bypass graft surgery in intensive care unit

Protocol summary

Summary

The single-blind controlled clinical trial study will be conducted with the purpose of determining the effect of family-centered care on the outcomes in patients undergoing coronary artery bypass graft surgery in intensive care unit in two 35 patient's intervention and control groups by using convenience sampling in the first step and random allocation in the second step in subspecialty Jamaran cardiac hospital. Study tools include: researcher made sheet for collecting patient's hemodynamic variables; Datex-ohmeda monitoring device for measuring hemodynamic parameters; Datex-ohmeda pulse oximetry device for measuring SPO2; Face anxiety scale (FAS) for measuring anxiety; and Richmond-agitation sedation scale (RASS) for measuring restlessness. Before operation day, in the first, speaking with patient and her/his family will be done and written consent form taken. Straightforward after patient entry to intensive care unit, the study will be commenced and after stability in clinical situation of patient, family member that learned her/his duties for existing in ICU during the patient was in operation room, will be entered in ICU and the study operationalized. For control group members, routine care will be done. After data collection, data will be entered in the SPSS software and analyzed.

General information

Acronym

Family-centered care

IRCT registration information

IRCT registration number: **IRCT201609014299N4**
Registration date: **2016-10-02, 1395/07/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-02, 1395/07/11

Registrant information

Name

Jamileh Mokhtari Nouri

Name of organization / entity

Baghiatallah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Nursing Faculty, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2016-09-20, 1395/06/30

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family-centered care on the outcomes in patients undergoing coronary artery bypass graft surgery in intensive care unit

Public title

Effect of family-centered care on the outcomes in patients undergoing coronary artery bypass graft surgery in intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1. Willingness of patient to participate in the study 2. Age between 18 and 75 years old 3. Performing cardiac surgery for the first time 4. Non-emergency cardiac surgery 5. Cardiac Ejection fraction more than 30% (EF>30%) 6. Lack of approved mental problems Exclusion criteria: 1. Bleeding more than 300 ml per hour in the first hour and requires surgical intervention 2. Occurrence of any neurological disorder after surgery 3. Unusual events in perioperative including pump time more than 2 hours or severe intraoperative bleeding 4. Hemodynamic instability during weaning that resulted in compromised patient safety and need to medical team intervention 5. Delay in weaning process according to the doctor's order 6. Return to operation room 7. Requirement the use of narcotic and sedative drugs more than common therapeutic protocol 8. Having Intra Aortic Balloon Pump (IABP) after surgery 9. Dependency rhythm to pacemaker 10. Existing coagulation problems 11. Receiving more than one type of inotropic drug or unusual doses after surgery

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Scienecs

Street address

Baqiyatallah University of Medical Scienecs, Shikh Bahaei street

City

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Postal code

Approval date

2015-10-23, 1394/08/01

Ethics committee reference number

IR.BMSU.REC.13940264

Health conditions studied

1

Description of health condition studied

Cardiac surgery

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Measurring variation in hemodynamic variables

Timepoint

Every ten minutes and totally seven times

Method of measurement

Researcher made questionnaire

Secondary outcomes

1

Description

Weaning during from mechanical ventilation

Timepoint

One time and in the end of work

Method of measurement

Researcher made checklist

Intervention groups

1

Description

In control group: No intervention will be done and only the routine care will be done.

Category

Behavior

2

Description

In intervention group: Presence of family member at the patient's bedside, observation, and speaking to her/his. Before the arrival of the family members at the patient's bedside, necessary explanations will be available for them through oral and written documents, understanding explanations by family members will be ensured by making questions and answers to those.

Category

Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Jamaran Subspecialty Cardiac hospital
Full name of responsible person
Dr Jamileh Mokhtari Nouri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr Afshin Pakjoo
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Sixth floor, Faculty Building, Baqiyatallah University of Medical Sciences, Tehran.
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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
Baqiyatallah 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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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