

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 912 248 8525

Email address

mokhtari@bmsu.ac.ir

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 Sciences

Street address

Baqiyatallah University of Medical Sciences, Shikh

Bahaei street

City

Tehran

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

Measuring 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

Street address

Jamaran Subspecialty Cardiac hospital, Jamaran

City

Tehran

Postal code

19575-174

Phone

+98 21824834095

Fax

+98 21824834095

Email

mokhtari@bmsu.ac.ir;

jamilmokhtari@yahoo.comsafaeepour@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr Jamileh Mokhtari nouri

Position

Assitant professor

Other areas of specialty/work**Street address**

Six floor, Faculty Building, Baqiyatallah University of Medical Sciences, Tehran.

City

Tehran

Postal code

19575-174

Phone

+98 21824834095

Fax

+98 21824834095

Email

mokhtari@bmsu.ac.ir;

jamilmokhtari@yahoo.comsafaeepour@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr Afshin Pakjoo

Street address

Sixth floor, Faculty Building, Baqiyatallah University of Medical Sciences, Tehran.

City

Tehran

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

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr Jamileh Mokhtari Nouri

Position

Assistant professor

Other areas of specialty/work**Street address**

Six floor, Faculty Building, Baqiyatallah University of Medical Sciences, Tehran.

City

Teharn

Person responsible for updating data

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Leila Safaeepour

Position

Student of master sciences in critical care nursing

Other areas of specialty/work**Street address**

Six floor, Faculty Building, Baqiyatallah University of Medical Sciences, Tehran.

City

Tehran

Postal code

824834095

Phone

+98 21824834095

Fax

+98 21824834095

Email

mokhtari@bmsu.ac.ir;

jamilmokhtari@yahoo.comsafaeepour@yahoo.com

Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>