Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of patient and family member preparation program before surgery on outcomes after coronary artery bypass graft

Protocol summary

Study aim

Determining effect of patient and family member preparation program before surgery on outcomes after coronary artery bypass graft

Design

Non-randomized clinical trial with control group, to prevent leakage of information, first the control group and then intervention group will be taken. The sample size will be 45 in each group. In both groups, the data will be collected on the first day of admission, the third and seventh day after surgery.

Settings and conduct

The place of the intervention is heart surgery department and ICU. Before the day of surgery in patients and family members are measured hospital anxiety and depression. then it will be measured on the seventh day of the surgery. The family member satisfaction and patient’s delirium is evaluated on the third day after surgery.

Participants/Inclusion and exclusion criteria

Patients age more than 18 years and less than 60, understanding Farsi, having mental health, lack of severe physical and mental disabilities, informed and free consent to participate in the study. The main caregiver is a member of the patient's family and during the hospital stay, will be accompanied by the patient, is adult and fluent in Farsi, have no open heart experience and no previous experience of care in the ICU. / History of dementia, psychosis and mental disorders, Emergency cardiac surgeries and the history of Cardiac surgeries and the use of off- pump surgical, death

Intervention groups

Intervention:The day before surgery, preparation program including 20 minutes of educational video for the patient and family member, and then patients participate in an individual tour of 10 to 15 minutes to ICU and Oral explanations are provided to the family members along with the educational booklet./ The control group will receive routine hospital care.

Main outcome variables

Hospital Anxiety and Depression, Satisfaction, Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161124031068N3**
Registration date: **2018-12-09, 1397/09/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-09, 1397/09/18**
Update count: **0**

Registration date

2018-12-09, 1397/09/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-03-30, 1398/01/10

Actual recruitment start date

2018-10-07, 1397/07/15

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of patient and family member preparation program before surgery on outcomes after coronary artery bypass graft

Public title

The effect of education on Cardiac Surgery patients and their family

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized for coronary artery bypass surgery Age over 18 years and under 60 years Understanding Persian language Having mental health Lack of severe physical and mental disability Having free and informed consent to participate in the study The patient has a primary caregiver who was a member of the family An adult family member Family member fluent in Farsi The family member has no open heart surgery experience and no previous experience of care in the intensive care unit

Exclusion criteria:

History of dementia, psychosis and known psychiatric disorders Emergency cardiac surgery History of Heart Surgery Use of off-pump surgical procedure

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Not 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 Tehran University of Medical Sciences

Street address

Nosrat St. Tohid Sq. School of Nursing Midwifery ,Tehran University of Medical Sciences

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Province

Tehran

Postal code

1419733171

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.TUMS.FNM.REC.1397.098

Health conditions studied

1

Description of health condition studied

The effect of preoperative preparation on outcomes of coronary artery bypass surgery

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Score of anxiety and depression in Hospital Anxiety and Depression Scale

Timepoint

On the first and seventh day of hospitalization of admission to the hospital

Method of measurement

Hospital anxiety and depression scale

2

Description

Satisfaction of the patient's family with ICU care

Timepoint

The third day of the patient's hospitalization in ICU

Method of measurement

Family satisfaction with intensive care unit questionnaire (FS-ICU)

Secondary outcomes

1

Description

Evaluation of patient's delirium after surgery

Timepoint

the third day after surgery

Method of measurement

Confusion Assessment in ICU(CAM-ICU)

Intervention groups

1

Description
Intervention group: Adult patients who undergo coronary artery bypass elective surgery will receive a preparation program the day before surgery, including a video clip, an ICU tour, and a training booklet.
Category
Prevention

2

Description
Control group: Adult patients who undergo coronary artery bypass elective surgery will receive routine hospital care.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyyed-al Shohada University Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Tehran University of Medical Sciences
Proportion provided by this source
70
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
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data will publish in group form and without any identification code.

When the data will become available and for how long

After approving the journal decision about acceptance and publication of the data as an article

To whom data/document is available

Editors of scientific journals

Under which criteria data/document could be used

No new analysis is permitted and the data can just use for information and checking quality and trustworthiness.

From where data/document is obtainable

Maryam Esmaeili, esmaeiliem@yahoo.com Anolin Aslan, aslan.anolin@gmail.com

What processes are involved for a request to access data/document

After receiving a request from editors, the research team will have a meeting and make a decision about which part of data can publish. Then, after declining any identification code, the data will send through email or fax.

Comments