

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Name

Maryam Esmaeili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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
City
 Tehran
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

Anolin Aslan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyedeh Fatemeh Vasegh Rahim Parvar

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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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Anolin Aslan

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr.Maryam Esmaeili

Position

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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