

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Comparative Study of the Effect of peer group and Orientation Program on patients' Anxiety Before Coronary Artery Bypass Graft (CABG) Surgery

#### Protocol summary

##### Summary

This study will be performed with the aim to compare and examine the effects of using peer group and orientation program on anxiety level of the patients before coronary artery bypass graft (CABG) surgery. In this clinical trial, 150 patients who are referred to Fatemeh Zahra educational hospital in Sari city (Iran) and are candidate for CABG surgery, are recruited through convenience sampling and then they are randomly assigned into two intervention groups including peer group and orientation program and one control group. There are 50 patients in each group. The inclusion criteria consist of: having CABG surgery for the first time, age more than 18 years old, being able to read and write, not having other serious physical and mental disorder, not having history of anxiety and depression and not using sedative drugs. The exclusion criteria are: not being consent to continue participation in the study, getting sick or not having normal hemodynamic conditions during research. Anxiety levels of all the patients are measured the day before surgery. Patients in the peer group are trained for one hour by similar patients who underwent successful CABG surgery in the past and in orientation program group they are taught for 30 minutes by the researcher in the suitable place in the critical care unit and operating room of the hospital. In control group no intervention is provided and they only receive routine care of the units. After intervention the anxiety level of the patients are measured one hour before CABG surgery.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2014102619677N1**

Registration date: **2014-12-01, 1393/09/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-01, 1393/09/10

##### Registrant information

###### Name

Ravanbakhsh Esmaeili

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3336 7345

###### Email address

r.esmaeili@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor of research, Mazandaran University of Medical Sciences

##### Expected recruitment start date

2014-10-21, 1393/07/29

##### Expected recruitment end date

2015-01-18, 1393/10/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative Study of the Effect of peer group and Orientation Program on patients' Anxiety Before Coronary Artery Bypass Graft (CABG) Surgery

##### Public title

Comparative Study of the Effect of peer group and Orientation Program on patients' Anxiety Before

Coronary Artery Bypass Graft (CABG) Surgery

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

The inclusion criteria consist of: having CABG surgery for the first time; age more than 18 years old, being able to read and write; not having other serious physical and mental disorder; not having history of anxiety and depression and not using sedative drugs. The exclusion criteria are: not being consent to continue participation in the study; getting sick or not having normal homodynamic conditions during research.

**Age**

From **18 years** old to **85 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study randomization includes random sampling by using block every week. The sampling starts for the group that randomly selected for the first week and then the second group is randomly selected for the second week and the sampling continues for the third group and this sequence is repeated until necessary number of patients are recruited.

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

**Street address**

Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences, Sari, Mazandaran

**City**

Sari

**Postal code**

4817844718

**Approval date**

2014-10-20, 1393/07/28

**Ethics committee reference number**

1183

**Health conditions studied**

1

**Description of health condition studied**

cvd

**ICD-10 code**

I25.1

**ICD-10 code description**

Atherosclerotic heart disease

**Primary outcomes**

1

**Description**

Anxiety

**Timepoint**

One day presurgery and one hour presurgery

**Method of measurement**

Spielberger state anxiety Inventory

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group1: peer group: In the peer group, patients are trained by someone who has a history of a successful coronary artery bypass graft (CABG) surgery for one hour. The education content includes CABG surgery and care before and after the operation.

**Category**

Other

2

**Description**

Intervention group2: Orientation program: In orientation program group, this program is provided by the researcher for 30 minute to become the patients familiar with the equipments of the ICU and operating room as well as care before and after coronary artery bypass graft (CABG) surgery. This education is provided in one day before the CABG surgery in the ICU and operating room.

**Category**

Other

3

**Description**

Control group: In control group no intervention is provided and they only receive routine care of the units.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Fatemeh Zahra Hospital, Mazandaran University of Medical Sciences

**Full name of responsible person**

Rahman Ghafari

**Street address**

Artesh Blv, Fatemeh Zahara Hospital, Mazandaran University of Medical Sciences, Sari, Mazandaran

**City**

Sari

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ethics committee of Mazandaran University of Medical Sciences

**Full name of responsible person**

Ahmad Ali Enayati

**Street address**

Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences, Sari, Mazandaran

**City**

Sari

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ethics committee of Mazandaran 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**

Mazandaran University of Medical Science

**Full name of responsible person**

Hadi Nematian Jelodar

**Position**

critical care Nursing M.Sc Student

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

Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences, Sari, Mazandaran

**City**

Sari

**Postal code**

4749115918

**Phone**

+98 11 3245 2384

**Fax**

+98 11 3245 4153

**Email**

nematian\_hadi@yahoo.com

**Web page address**

-

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ravanbakhsh Esmaeili

**Position**

Ph.D

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

Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences, Sari, Mazandaran

**City**

Sari

**Postal code**

009833367345

**Phone**

0011

**Fax**

-

**Email**

r.esmaeili90@gmail.com

**Web page address**

-

**Person responsible for updating data****Contact****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*