

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of family presence on anxiety of acute coronary syndrome patients at cardiac care unit.

Protocol summary

Summary

This study will be done with the aim of investigating the effect of family presence on anxiety of acute coronary syndrome patients at cardiac care unit. Convenient samples will be used. Inclusion criteria: Acute coronary syndrome patients who are hospitalized for at least three days in cardiac care unit; The patient is alert and awake; Gaining Score higher than 20 according to speilberger questionnaire. Exclusion criteria: Discharging patient less than three days of hospitalization; Cardiopulmonary resuscitation need; Reciving hypnotic except for Alprazolam and Oxazepam; The presence of acute cardiovascular and pulmonary complications during the study. A quasi-experimental study will be started on 60 acute coronary syndrome patients and patients will be divided into two categories, after doing steps of beginning the study and obtaining approval and written consent. Speilberger questionnaire will be used for the level of anxiety evaluation. A member of family who has had close emotional relationship with the patient will be stayed beside him/her for the intervention group, from beginning until third day of hospitalization as well as usual cares. Routine cares without family presence will be done for control group. As the average time of hospitalization in cardiac care unit in this center is 72 hours, the questionnaire will be completed once in a first and the second time in third day of hospitalization. Then the effect of family presence on patient's anxiety will be assessed and compared in both groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017030732939N1**

Registration date: **2017-09-02, 1396/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-02, 1396/06/11

Registrant information

Name

Leila Hatefpartovi

Name of organization / entity

Faculty of Nursing and Midwifery of Shahid Beheshti
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Faculty of Nursing and Midwifery of Shahid Beheshti
University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family presence on anxiety of acute coronary
syndrome patients at cardiac care unit.

Public title

Effect of family presence on anxiety of acute coronary
syndrome patients at cardiac care unit.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Acute coronary patients (ST Elevation MI; Non ST Elevation MI; Unstable Angina) be hospitalized for at least three days in cardiac care unit; Awareness of place and time; No psychological disorder with physician's approval. Gaining score higher than 20 according to Spielberger questionnaire. Exclusion criteria: Discharging patient who is hospitalized for less than three days; Cardiopulmonary resuscitation need; Receiving hypnotic except for Alprazolam and Oxazepam which is usually prescribed by the physician; The presence of acute cardiovascular and pulmonary complications such as Acute Pulmonary Edema, Heart Failure and Angina during the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Assignment of study groups is parallel.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Faculty of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences

Street address

Valiasr St, Niayesh Intersection, Across from Shahid Rajaei Hospital Faculty of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

1985717443

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

IR.SBMU.PHNM.1395.571

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Disorder (of) anxiety

Primary outcomes**1****Description**

Anxiety

Timepoint

First and Third day of Patient's hospitalization

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Without action/ Routine cares without family presence beside patient during the hospitalization and assessing the level of patient's anxiety in first and third day of hospitalization.

Category

N/A

2**Description**

Intervention group: patient's family presence from the first day until the third day of hospitalization and assessing the level of patient's anxiety in first and third day and at last comparing with control group.

Category

Other

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

EmamReza Hospital in Eslam Shahr

Full name of responsible person

Dr. Sima Zohari Anboohi

Street address

valiasr St, Niayesh Intersection, Across from Shahid

Rajaei Hospital, Faculty of Nursing and Midwifery of
Shahid Beheshti University of Medical Sciences,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

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Tehran, Iran

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti
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

Faculty of Nursing and Midwifery of Shahid Beheshti
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Full name of responsible person

Leila Hatef Partovi

Position

M.S. Student of Nursing

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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