

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Effect of nursing counseling on self-efficacy of patients with acute coronary syndrome

#### Protocol summary

##### Study aim

Determining the Effect of nursing counseling on self-efficacy of patients with acute coronary syndrome

##### Design

Clinical trial with control group with parallel groups, without blindness, randomized

##### Settings and conduct

In this study, 120 patients with acute coronary syndrome admitted to the coronary Care Unit of Imam Hossein Hospital in Shahroud will be selected based on the criteria of the researcher and will be randomized in the intervention and control group. Nursing counseling will be conducted for the intervention group.

##### Participants/Inclusion and exclusion criteria

Entry criteria: The patient's presence on the third day in the hospital (the day the consultation process starts in the hospital), Earn less than 32 scores from Sullivan self-efficacy questionnaire (Self-efficacy Scherer), Patients with acute coronary syndrome (unstable angina, myocardial infarction) 35-70 years old, Ability to speak and understand Persian language Exit criteria: Unwillingness to continue cooperation in the study, Creating complications such as: cardiopulmonary arrest, resistant ventricular arrhythmia, cardiogenic shock following illness, death

##### Intervention groups

In the first stage, the patient will be trained face to face about: the definition of acute coronary syndrome, the risk factors and symptoms of heart disease, the effect of disease on work and life and sexual relations and social activities, diet and drugs, and complications of non-compliance, in 20 minutes. In the next step, one week after the intervention, a telephone consultation will take place for 10 minutes and will be questioned about the treatment and use of medications, diet and self-care. In the final stage, three weeks after the first training, a 10-minute telephone consultation will be carried out on follow-up care at home and adherence to the medication.

##### Main outcome variables

Self-efficacy of patient

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100114003064N9**

Registration date: **2018-06-25, 1397/04/04**

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

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

##### Registration date

2018-06-25, 1397/04/04

##### Registrant information

##### Name

Hossein Bagheri

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3239 5054

##### Email address

bagheri@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2018-12-21, 1397/09/30

##### Actual recruitment start date

2018-06-22, 1397/04/01

##### Actual recruitment end date

2018-12-21, 1397/09/30

**Trial completion date**

empty

**Scientific title**

Effect of nursing counseling on self-efficacy of patients with acute coronary syndrome

**Public title**

Nursing counseling and self-efficacy of patients with acute coronary syndrome

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patient's presence on the third day in the hospital (the day the consultation process starts in the hospital)  
 Earn less than 32 scores from Sullivan self-efficacy questionnaire (Self-efficacy Scherer) Patients with acute coronary syndrome (unstable angina, myocardial infarction) 35-70 years old Ability to speak and understand Persian language

**Exclusion criteria:**

Unwillingness to continue cooperation in the study  
 Creating complications such as: cardiopulmonary arrest, resistant ventricular arrhythmia, cardiogenic shock following illness, death

**Age**From **35 years** old to **70 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into two groups by block of 4: A (nursing counseling) and B (control group). The allocation will be done concealment. In this way, there will be 70 envelopes, each with A and B codes. The envelopes will be numbered. Individuals will be coded according to their entry into the study, and will be allocated an envelope for each patient to the group

**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 Shahroud University of Medical Sciences

**Street address**

Haft-Tir square

**City**

Shahroud

**Province**

Semnan

**Postal code**

3614773955

**Approval date**

2018-05-30, 1397/03/09

**Ethics committee reference number**

ir.shmu.rec.1396.202

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

Acute coronary syndrome

**ICD-10 code**

I25.9

**ICD-10 code description**

Chronic ischaemic heart disease, unspecified

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

Self-efficacy score in Sullivan self-efficacy questionnaire in people with scores of less than 32

**Timepoint**

Self-efficacy measurement as soon as the patient's condition improves before the intervention begins and one month after the intervention

**Method of measurement**

Sullivan self-efficacy questionnaire

**Secondary outcomes**

empty

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

Intervention group: In the first stage, the patient will be trained face to face bout: the definition of acute coronary syndrome, the risk factors and symptoms of heart disease, the effect of disease on work and life and sexual relations and social activities, diet and drugs, and complications of non-compliance, in 20 minutes. In the next step, one week after the intervention, a telephone consultation will take place for 10 minutes and will be questioned about the treatment and use of medications,

diet and self-care. In the final stage, three weeks after the first training, a 10-minute telephone consultation will be carried out on follow-up care at home and adherence to the medication.

**Category**

Prevention

**2****Description**

Control group: The control group will not receive intervention and will only receive routine care and care at the hospital and discharge time.

**Category**

Prevention

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

Imam Hossein Hospital

**Full name of responsible person**

Dr. Hoseein Bagheri

**Street address**

28-meter Touhidi, Imam Khomeini Street

**City**

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bagheri@shmu.ac.ir

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<http://eh.shmu.ac.ir/home.html>

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

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad-Hassan Emamian

**Street address**

Haft Tir Square

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emamian@shmu.ac.ir

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<http://research.shmu.ac.ir>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahroud University of Medical Sciences

**Proportion provided by this source**

100

**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**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Bagheri

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

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**Full name of responsible person**

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Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahrood University of Medical Sciences  
**Full name of responsible person**  
Dr. Hossein Bagheri  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Hafte-Tir Square  
**City**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no more information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available