Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect Of Spiritual Care On Post Traumatic Stress Disorder Following Acute Myocardial Infarction

Protocol summary

Study aim

Determining the mean score of post traumatic stress in patients in the intervention group. Determining the mean score of post traumatic stress in patients in the control group. Comparison of mean score of post traumatic stress disorder in the control and intervention group.

Design

This is a clinical trial with control group in which 80 patients with acute myocardial infarction, who have inclusion criteria, will be selected, and they are divided into two groups by block method.

Settings and conduct

This study will be conducted in the coronary care unit of Amir Kabir Hospital in Arak. Spiritual care is provided by the nurses who have received adequate training in this regard.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient has an acute myocardial infarction; according to a cardiologist's diagnosis; Being alert; Speaking in Persian; Being Muslim; Have no known mental illness; Have no mental retardation. Exit criteria: Unwillingness to continue the study; Occurrence of a new heart attack; Occurrence of any severe complications of myocardial infarction (cardiogenic shock and severe heart failure); The necessity of using a pacemaker and implantable cardioverter defibrillator; ;Performing a coronary artery bypass graft surgery; Patient death; Displacement of the patient's place of residence.

Intervention groups

For patients in the intervention group, the spiritual care program includes three sessions. Each session is held for half an hour and three consecutive days.For patients in the control group, the usual care is performed.

Main outcome variables

The post traumatic stress disorder checklist is a commonly used tool for investigating the incidence of post traumatic stress disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180903040935N1**
Registration date: **2018-11-25, 1397/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-25, 1397/09/04**
Update count: **0**

Registration date

2018-11-25, 1397/09/04

Registrant information

Name

Zohreh Ababaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3503

Email address

mozo16883@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Spiritual Care On Post Traumatic Stress Disorder Following Acute Myocardial Infarction

Public title
The Effect Of Spiritual Care On Post Traumatic Stress Disorder
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The patient has an acute myocardial infarction, according to a cardiologist's diagnosis. Being alert. Speaking in Persian. Being Muslim. Have no known mental illness. Have no mental retardation.
Exclusion criteria:
Unwillingness to continue the study. Occurrence of a new heart attack. Occurrence of any severe complications of myocardial infarction (cardiogenic shock and severe heart failure). The necessity of using a pacemaker and implantable cardioverter defibrillator. Performing a coronary artery bypass graft surgery. Patient death. Displacement of the patient's place of residence.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be selected according to inclusion and exclusion criteria and will be randomly divided into intervention and control groups by blocked randomization using computer software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Vice-Chancellor for Research, Arak University of Medical Sciences, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2018-09-23, 1397/07/01
Ethics committee reference number
1397.156

Health conditions studied

1

Description of health condition studied
Acute Myocardial Infarction
ICD-10 code
121
ICD-10 code description
121.0, 121.1, 121.2, 121.3, 121.4, 121.9

Primary outcomes

1

Description
Score of post traumatic stress disorder.
Timepoint
One month after the start of the study.
Method of measurement
Post Traumatic Stress Disorder Checklist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The participants of the intervention group undergo spiritual need-based program. This program consisted of a 30 minute session per day for 3 consecutive days. The first session focuses on reducing concerns about the future by explaining Truth. In the second session, promotion of self-esteem is considered by explaining self-esteem and eliminating its conflicts. At the third session, emphasis is placed on reducing feelings of guilt and attaining calm. one month later, Post Traumatic Stress Disorder Checklist (PCL) will be completed by patients.
Category
Prevention

2

Description
Control group: Patients in the control group receive routine care. one month later, Post Traumatic Stress

Disorder Checklist (PCL) will be completed by patients.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir hospital

Full name of responsible person
Zohreh Ababaei

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https://amirkabirhos.arakmu.ac.ir/Portal/Home/Default.aspx

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohammad Arjomandzadegan

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Zohreh Ababaei

Position
Master,s student critical care nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Nursing school, Payambar Azam Complex, Basij Square, Sardasht Arak

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Korosh Rezaei

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zohreh Ababaei

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Bachelor of Nursing

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic characteristics and post traumatic stress score.

When the data will become available and for how long

Start the access period 6 months after the publication of the results.

To whom data/document is available

All individuals can access the information.

Under which criteria data/document could be used

Nothing.

From where data/document is obtainable

Korosh Rezaei; k.rezaei@arakmu.ac.ir; Arak University of Medical Sciences; 00989183677622.

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

Two weeks after the applicant's request.

Comments