

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

I21

ICD-10 code description

I21.0, I21.1, I21.2, I21.3, I21.4, I21.9

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

Street address

Alamoll Huda Street

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Phone

+98 86 3313 4717

Fax

+98 86 3313 2510

Email

it@arakmu.ac.ir

Web page address

<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

Street address

Basij Square, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

6941738481

Phone

+98 86 3417 3638

Email

Research@arakmu.ac.ir

Web page address

<https://oldvcr.arakmu.ac.ir/Portal/home>

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

Street address

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

City

Arak

Province

Markazi

Postal code

384876941

Phone

+98 86 3417 3524

Fax

+98 86 3417 3524

Email

mozo16883@yahoo.com

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

Street address

Arak university of Medical Sciences, Alamoll Huda Street, Railroad Street

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3524

Email

k.rezaei@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Zohreh Ababaei

Position

Bachelor of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Arak university of Medical Sciences, Alamoll Huda
Street, Railroad Street

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3313 6055

Email

mozo16883@yahoo.com

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