Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of spiritual care based on GHALBE SALIM Model on spiritual health and quality of life of patients with Acute MI hospitalized in CCU

Protocol summary

Summary

This study aimed to evaluate the effect of spiritual care based on GHALBE SALIM model on spiritual health and quality of life of patients with acute MI. The study is a randomized, non-blinded clinical trial. The study population includes all patients with acute MI hospitalized in Alzahra hospital affiliated to Isfahan University of Medical Sciences. Inclusion criteria: Consent for participation in study; age more than 50 years; diagnosed with acute MI by cardiologist; being Iranian and Shia; being conscious. Exclusion Criteria: Patient's unwillingness to cooperate; experience of stressful events; transfer to other units or hospitals; death. Sample size includes 60 patients. After getting informed consent in test group, they will complete spiritual health and quality of life questionnaires as primary and secondary outcomes. Care-plan based on GHALBE SALIM model (Quad communications reform educations according to GHALBE SALIM model) will implement for them. Finally, aforementioned questionnaires will complete for patients again at the end of the study. Control group is similar to test group but for this group we will not implement care-plan based on GHALBE SALIM model and they will receive routine care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606208665N5**
Registration date: **2016-06-30, 1395/04/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-06-30, 1395/04/10

Registrant information

Name
Hassan Babamohamadi
Name of organization / entity
Semnan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 23 3365 4190
Email address
babamohamadi@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Semnan University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2017-09-11, 1396/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care based on GHALBE SALIM Model on spiritual health and quality of life of patients with Acute MI hospitalized in CCU

Public title

The effect of spiritual care on spiritual health and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Consent for participation in study; age more than 50 years; diagnosed as acute MI by

cardiologist; Iranian origin and Shia; being conscious. Exclusion Criteria: Patient's unwillingness to cooperate ; experience of stressful events; transfer to other units or hospital; death

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Random allocation of subjects to experimental and control groups will be carried out using sealed envelopes in which the letters A or B will be placed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Vice Chancellor for Research and Technology, Basidj Blv, Semnan, Iran

City
Semnan

Postal code
3513138111

Approval date
2016-06-20, 1395/03/31

Ethics committee reference number
IR.SEMUMS.REC.1395.53

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction

ICD-10 code
121

ICD-10 code description
Acute myocardial infarction

Primary outcomes

1

Description
Spiritual Health

Timepoint
At the begining and at end of study

Method of measurement
Palutzian and Ellison spiritual health questionnaire

Secondary outcomes

1

Description
Quality of life

Timepoint
At the begining and at the end of study

Method of measurement
WHOQOL-BRIEF questionnaire

Intervention groups

1

Description
After getting informed consent in test group, they will complete spiritual health and quality of life questionnaires. Spiritual care-plan based on GHALBE SALIM model will implemented for them. This program will be implemented for three day in CCU when patients feel lonely and spiritual issues appear between 17-20 hours and continue for one month after discharge by patients themselves. After one month aforementioned questionnaires will complete for patients again.

Category
Lifestyle

2

Description
After getting informed consent in control group, they will complete spiritual health and quality of life questionnaire. But spiritual care-plan based on GHALBE SALIM model will not implement for them and they will receive only routine nursing care.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Alzahra Hospital

Full name of responsible person
Hassan Babamohamadi
Street address
CCU, Alzahra Hospital, Isfahan
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Semnan University of Medical Sciences
Full name of responsible person
Dr Ali Rashidypour
Street address
Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran
City
Semnan
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 Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Hassan Babamohamadi
Position
Assistant Professor
Other areas of specialty/work
Street address
Nursing and Allied Health Faculty, Semnan University of Medical Sciences, 5th Kilometer of Damghan Road, Semnan, Iran
City
Semnan
Postal code
3513138111
Phone
+98 23 3365 4190
Fax
Email
babamohammady2007@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Hassan Babamohamadi
Position
Assistant Professor
Other areas of specialty/work
Street address
Nursing and Allied Health Faculty, Semnan University of Medical Sciences, 5th Kilometer of Damghan Road, Semnan, Iran
City
Semnan
Postal code
3513138111
Phone
+98 23 3365 4190
Fax
Email
babamohammady2007@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Hassan Babamohamadi
Position
Assistant Professor
Other areas of specialty/work
Street address
Nursing and Allied Health Faculty, Semnan University of Medical Sciences, 5th Kilometer of Damghan Road, Semnan, Iran
City
Semnan
Postal code
3513138111
Phone
+98 23 3365 4190
Fax
Email
babamohammady2007@gmail.com
Web page address

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