

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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 beginning and at end of study

Method of measurement

Palutzian and Ellison spiritual health questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

At the beginning 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

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Isfahan

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Web page address**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

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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