

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of spiritual care On Chest Tube Removal Anxiety And pain In Patients Open Heart Surgery

Protocol summary

Study aim

The Effect of Spiritual Care on Pain Anxiety and Pain in Open Heart Surgery Patients.

Design

80 patients are considered open heart surgery. Non Randomly, 40 were in the spiritual care group and 40 in the control group. Spiritual care for the intervention group begins after surgery and is removed from the ventilator, after full awakening, and continues until the first chest tube is removed. The research assistant does not know the patient grouping, and Patients are asked to rate their pain severity in three stages (before, immediately and 10 minutes after chest tube removal) based on the Visual Analogue Scale (pain). Half an hour before the chest tube is removed, visual analogue scale (anxiety) is used.

Settings and conduct

Following the necessary arrangements, the study sample will be selected from the Afshar open heart surgery patients who have the inclusion criteria, one day before the cardiac surgery. The research sample is selected. The method and purpose of the research are explained. They were non randomly assigned to intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with open heart surgery who have at least one chest tube. The patient should be alert and alert. The patient should not be under ventilator. Minimum age 20 years and maximum 75 years. Exclusion criteria: Patients with severe hearing impairment. Have a history of cognitive and mental problems.

Intervention groups

In the intervention group, one day before open heart surgery, the spiritual care program is tailored to patients' needs and desires, including the presence of support, support for the patient's religious rituals, and use of support systems. The control group performs routine care.

Main outcome variables

pain, Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200106046025N1**

Registration date: **2020-01-17, 1398/10/27**

Registration timing: **prospective**

Last update: **2020-01-17, 1398/10/27**

Update count: **0**

Registration date

2020-01-17, 1398/10/27

Registrant information

Name

Hossin FasihiZadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3821 6513

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-18, 1398/10/28

Expected recruitment end date

2020-02-17, 1398/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of spiritual care On Chest Tube Removal Anxiety And pain In Patients Open Heart Surgery

Public title

spiritual care On Chest Tube Removal Anxiety And pain Open Heart Surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Open heart surgery patients with at least one chest tube
The patient should be alert and awake and not having a ventilator device. The patient is willing to participate in the study. Minimum age of 20 years and maximum of 75 years

Exclusion criteria:

Patients with a history of cognitive and mental problems
Patients with severe hearing impairment

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Clinical caregivers and outcome assessors and data analysts do not know the control and test patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yazd University of Medical Sciences Shahid Sadoughi

Street address

Shahid Sadoughi University of Medical Sciences,
Bahonar Square, Yazd

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Province

Yazd

Postal code

8916978477

Approval date

2020-01-05, 1398/10/15

Ethics committee reference number

IR.SSU.REC.1398.161

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

Coronary heart bypass

ICD-10 code

T82.2

ICD-10 code description

Mechanical complication of coronary artery bypass graft and biological heart valve graft

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

pain

Timepoint

before, during and 10 minutes after removal chest tube

Method of measurement

Visual Analogue Scale (pain)

2**Description**

Anxiety

Timepoint

before removal chest tube

Method of measurement

Visual Analogue Scale (Anxiety)

Secondary outcomes

empty

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

Intervention group: In order to provide spiritual care for the intervention group after the patient is fully awake and awake after surgery, the researcher introduces himself to the patient, and with the expression of professional abilities, tries to gain the patient's trust because of the patient's participation in care delivery and acceptance. How they care is one of the essential pillars of spiritual care. chest tube removal is performed

by a researcher, and female patients by a trained female nurse. Patients who have two or three tubes are considered the first tube to be removed. Patient anxiety was measured by a research assistant (who was unaware of patient grouping), half an hour before removal chest tube, with the Visual Analogue Scale (Anxiety). The patient's pain was measured before, immediately and ten minutes after the chest tube was removed, using a visual analogue scale (pain).

Category

Treatment - Other

2

Description

Control group: The usual care is to remove the chest tube.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital

Full name of responsible person

Hossin Fasihizadeh

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Jomhuri Blvd, Afshar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.M.Mirezaee

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Khadijeh Nasiriani

Position

ph.D of Nursing

Latest degree

Ph.D.

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

Hossin Fasihizadeh

Position

Student Nurse in master of critical care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

Yazd

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available