

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of comfort- based nursing cares on their perception of nursing care behaviors and comfort level among patients undergoing open heart surgery

Protocol summary

Summary

This study is a randomized controlled clinical trial and research environment is intensive care unit at the Golestan heart center in the Kordkoy town. The aim of study is to determine the effects of comfort centered care on patients' comfort and patients' perception of nursing care behaviors in open-heart surgery patient. Sample size is determined through a pilot study. Then patients who are selected based on inclusion criteria will be randomly allocated to experimental and control groups. Randomization will be done through block randomization. Totally 70 patients will be enrolled. Interventions: intervention group will receive planned care including reflexotherapy and open heart surgery care education through face-to-face education and pamphlets and modification of environmental factors. All interventions will be done at a fixed time in each day during six consecutive days and patients will complete HCQ and CBI questionnaires 24 hour six days after surgery and intervention. Control group will receive only routine care. Inclusion criteria: being at the age of 25 to 60 years; the willingness to participate in the study; signing an informed consent; complete consciousness of the patient; not being emergency surgery, the ability to make a verbal communication; the ability to read and write; there are no scratches, scars, corn, infection or any loss and damage in the feet; no history of mental illness or addiction and absence of vision or hearing impairments; PTT in the range of 30 to 60. The main outcomes in this study are comfort level and its dimensions and patients' perception of care behaviors and its dimensions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032733153N1**

Registration date: **2017-04-16, 1396/01/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-16, 1396/01/27

Registrant information

Name

Fatemeh Sheikhy

Name of organization / entity

Birgand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1410

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fa.sheikhy@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birgand University of Medical Sciences and Investigator

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of comfort- based nursing cares on their perception of nursing care behaviors and comfort level among patients undergoing open heart surgery

Public title

The effect of comfort- based nursing cares on the perception of care behaviors and comfort

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being at the age of 25 to 60 years; the willingness to participate in the study; signing an informed consent; complete consciousness of the patient; not being emergency surgery, the ability to make a verbal communication; the ability to read and write; there are no scratches, scars, corn, infection or any loss and damage in the feet; no history of mental illness or addiction and absence of vision or hearing impairments; PTT in the range of 30 to 60.

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

allocate patients to permutation blocking manner to experimental and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birgand University of Medical Sciences

Street address

Birgand University of Medical Sciences; Ayatollah Ghaffari street; Birjand; South Khorasan

City

Birgand

Postal code

9717853577

Approval date

2017-01-02, 1395/10/13

Ethics committee reference number

IR.bums.REC.1395.232

Health conditions studied

1

Description of health condition studied

open heart surgery

ICD-10 code

I97.1

ICD-10 code description

Other functional disturbances following cardiac surgery

Primary outcomes

1

Description

Patients' perception of nursing care behaviors

Timepoint

24 hour after surgery and before intervention and six days after intervention

Method of measurement

Caring Behavior Inventory Questionnaire

2

Description

Comfort

Timepoint

24 hour after surgery and before intervention and six days after intervention

Method of measurement

Hospice comfort questionnaire

Secondary outcomes

1

Description

comfort Physical dimension

Timepoint

24 hours after surgery and before the intervention and after the intervention in Six days.

Method of measurement

score of Physical Dimension of comfort questionnaire

2

Description

comfort psychological dimension

Timepoint

24 hours after surgery and before the intervention and after the intervention in Six days.

Method of measurement

score of psychological Dimension of comfort questionnaire

3

Description

Comfort environmental dimension

Timepoint

24 hour after surgery and before the intervention and after the intervention on sixth day.

Method of measurement

Score of environmental Dimension of comfort questionnaire

4

Description

comfort social dimension

Timepoint

24 hour after surgery and before the intervention and after the intervention in Six days.

Method of measurement

score of social Dimension of comfort questionnaire

5

Description

Respect others dimension

Timepoint

24 hour after surgery and before the intervention and after the intervention in Sixth day.

Method of measurement

score of Respect others dimension

6

Description

Assurance of human presence Dimension

Timepoint

24 hour after surgery and before the intervention and after the intervention in Six days.

Method of measurement

Assurance of human presence Dimension score

7

Description

Positive Communication and attitude Dimension

Timepoint

24 hour after surgery and before the intervention and after the intervention on Sixth days.

Method of measurement

Positive Communication and attitude Dimension score

8

Description

Knowledge and Professional skills dimension

Timepoint

24 hours after surgery and before the intervention and after the intervention in Six days.

Method of measurement

Knowledge and Professional skills dimension score

9

Description

Attention to others' experiences dimension

Timepoint

24 hour after surgery and before the intervention and after the intervention on sixth day.

Method of measurement

Attention to others' experiences dimension score

Intervention groups

1

Description

Intervention group: Interventions include modification of environmental lights, devices' alarm and personnel sounds and reflexotherapy in reflective chest point under the thumb of the left foot and cardiac surgery care training through face-to-face education and pamphlets. Interventions will be implemented during six consecutive days at 17 o'clock.

Category

Rehabilitation

2

Description

Control group will receive only routine care. Pamphlets will be given to patients on sixth day in order to comply with the ethical principles.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kordkoy Amiralmoomenin Hospital

Full name of responsible person

Dr.GholamAli Riaahy

Street address

Amiralmoomenin Hospital, Jangal street, Kordkoy, Golestan Province

City

Kordkoy

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Birjand University of Medical Sciences

Full name of responsible person

Shahnaz Tabiee

Street address

Birjand University of Medical Sciences; Ayatollah Ghaafari street; Birjand; South Khorasan

City

Birjand

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, Birgand 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**

Birgand University of Medical Sciences

Full name of responsible person

Fatemeh Sheikhy

Position

Master Student in Nursing

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Faculty member

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Full name of responsible person

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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