Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessing the Effects of Implementation of Comfort Caring Model on Distress, Pain, and Hemodynamic Parameters of Children with Congenital Heart Disease Following the Cardiac Surgery

Protocol summary

Study aim

Determining the Effects of Implementation of Comfort Caring Model on Distress, Pain, and Hemodynamic Parameters of Children with Congenital Heart Disease Following the Cardiac Surgery

Design

In this study, 50 children with congenital heart disease,which have open heart surgery,are selected according to entrance criteria. Participants are randomly divided into intervention and control groups. For sampling, random blocking sampling is used. In the intervention group interventions begin for each sample immediately after surgery and upon entering the cardiac care unit of children, according to comfort theory ,that provided at three levels of relief, ease and transcendence in the form of four dimensions of physical, environmental, psycho Spiritual and SocioCultural. A care plan is being developed and used during the intervention period to take care of the child. This program is reviewed in any shift. The control group carries out post-operative care, this care is based on in-patient policies and in-patient care protocols related to nursing care after surgery for pediatric cardiopulmonary abnormalities. Same Nurses care for children in both intervention and control groups, with the difference that they perform routine care in the control group and act in the intervention group according to the care plan developed according to the comfort theory. The intervention period for Every child will be 72 hours "beginning of the study, after 24, 48 and 72 hours" during this time three variables including psychological distress, pain and hemodynamic conditions of the patient, including vital signs, arterial blood oxygenation, serum lactate levels, mean arterial pressure, and central venous pressure are measured in both intervention and control groups.

Settings and conduct

This study is a clinical trial of two randomized groups for children who are admitted to the pediatric intensive care unit of Shahid Rajaee Hospital after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria :child with cardiac abnormalities Parental satisfaction for participate in the study after undergo open heart surgery Lack of chromosomal abnormalities and mental retardation Non-treatment with neuromuscular blockers drugs Age of the child: from 28 days until the end of two years having no history of previous hospitalization and performing surgery for the first time having a CV line Connection to the mechanical ventilation device at the time of admission and separation within the first 24 hours after surgery;Exclusion criteria: Death of a child Dissatisfied parents to continue implementing a care method based on the comfort theory Incidence of unpredictable effects after surgery

Intervention groups

This study will be conducted on children with congenital heart disease after heart surgery in a pediatric intensive care unit. After surgery when the children come to pediatric care unit from operation room , children who are eligible for entry and exit criteria are selected and randomly assigned to intervention and control groups. In the intervention group, nursing care based on comfort care theory is performed in three levels of relief, ease and transcendence in the form of four dimensions of physical, environmental, psych-spiritual, and sociocultural. The control group will receive usual post-operative care. Their care program will be based on in-patient policies and in-patient care protocols related to nursing care after surgery for pediatric cardiopulmonary abnormalities. Caregiver nurses are the same in both groups, with the difference that they care based on usual care program in the control group, and in the intervention group, care is based on a care plan designed according comfort theory.

Main outcome variables

The outcome of a care program based on comfort theory

on pain, psychiatric disturbance and some hemodynamic parameters of children including vital signs, arterial blood oxygenation, serum lactate levels, arterial pressure, and central venous pressure are investigated.

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20101113005163N6**
Registration date: **2018-01-03, 1396/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-03, 1396/10/13**
Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Akram sadat Sadat hoseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6653 2998

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ashoseini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

This research, which is a master's degree dissertation, will be conducted as a research project at the University of Nursing and Midwifery Faculty of Tehran University of Medical Sciences, and all costs will be paid by the University.

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-02-04, 1396/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the Effects of Implementation of Comfort Caring Model on Distress, Pain, and Hemodynamic Parameters of Children with Congenital Heart Disease Following the Cardiac Surgery

Public title

Assessing the Effects of Implementation of Comfort Caring Model on Distress, Pain, and Hemodynamic Parameters of Children with Congenital Heart Disease Following the Cardiac Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

child with cardiac abnormalities Parental satisfaction for participate in the study after undergo open heart surgery Lack of chromosomal abnormalities and mental retardation Non-treatment with neuromuscular blockers drugs Age of the child: from 28 days until the end of two years having no history of previous hospitalization and performing surgery for the first time having a CV line Connection to the mechanical ventilation device at the time of admission and separation within the first 24 hours after surgery

Exclusion criteria:

Death of a child Dissatisfied parents to continue implementing a care method based on the comfort theory Incidence of unpredictable effects after surgery

Age

From **28 days** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, random blocking sampling method is used. The researcher selects his samples from eligible children at a specified time interval. Assignment of samples is done in two experimental and control groups by random method and the completion of the samples is continued. Block random sampling is a randomized method that ensures that at each point in a research, roughly equal numbers of participants are assigned to all the comparison groups. To randomly assign samples to test groups and Random blocking control is the best method and it is possible to achieve the same number of samples in groups in sequential or sequential sampling at any time point of the study. The number of blocks based on the sample size determined according to the pilot study .

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of the Research Committee of Midwifery Faculty, Tehran University of Medical Sc

Street address
Nosrat St,Tohid Square

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2017-07-04, 1396/04/13

Ethics committee reference number
IR.TUMS.FNM.REC.1396.2788

Health conditions studied

1

Description of health condition studied
Check distress, pain and hemodynamic parameters in children with congenital heart defects after open heart surgery

ICD-10 code
Q24.9

ICD-10 code description
Acyanotic and cyanotic congenital heart disease

Primary outcomes

1

Description
distress

Timepoint
On arrival, 24, 48, 72 hours after surgery and entering to PICU

Method of measurement
comfort behavior scale

2

Description
pain

Timepoint
On arrival, 24, 48, 72 hours after surgery and entering to PICU

Method of measurement
comfort behavior scale

3

Description
hemodynamic parameters

Timepoint
On arrival, 24, 48, 72 hours after surgery and entering to PICU

Method of measurement
comfort behavior scale

Secondary outcomes

empty

Intervention groups

1

Description
1) Intervention group: The intervention in this group is the implementation of a nursing care program based on the nursing theory of comfort. Nurses carry out three levels of interventions for the care of children in the intervention group after surgery based on comfort theory. These three levels include relief, ease and transcendence in four aspects of physical, psycho spiritual, socio-cultural and environmental care. Interventions in the physical aspect include the establishment and maintenance of homeostasis in the body, maintaining water and electrolyte balance, oxygenation, temperature adjustment, heart rhythm monitoring, gastrointestinal stability, nervous system, respiratory system, circulation system Blood and disfiguring system. Another aspect of care is the psycho spiritual dimension, nursing care is touching, encouraging words, special appointments, and self-esteem strategies. The third dimension is the socio-cultural dimension, which includes support, attention to cultural sensitivities, the use of body language in the proper manner, and the care that is being taken to achieve it, including providing appropriate information about procedures, family presence And donations, respect for cultural traditions. The last one is the environmental dimension including silence, order, security, light and ambient control, ambient temperature control, avoidance of falling sleep rhythm and awakening and control of odor.

Category
Other

2

Description
Control group: The control group will usual receive post-operative care. Regular care will be performed based on internal policies and care protocols related to nursing care after surgery for pediatric cardiopulmonary abnormalities.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaee Cardiology Hospital

Full name of responsible person
Akramsadat Sadat- Hoseini
Street address
District 3, Hashemi Rafsanjani Expy, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Modares
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Faculty of Nursing and Midwifery, Nosrat St,Tohid Square, Tehran, Iran
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ashoseini@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Akramsadat Sadat Hosieni
Position
Nursing PHD
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no program for publishing participant data file.
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