

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the effect of a care program on the frequency of occurrence and progression of impaired skin integrity in one-month to six-year-old children following an open-heart surgery

Protocol summary

Study aim

Determination and comparison of the effect of a care program on the frequency of occurrence and progression of impaired skin integrity in children following an open-heart surgery

Design

A single-blinding clinical trial, with the parallel groups

Settings and conduct

In this study, 80 children who are candidates for open-heart surgery will be included in the study and will be randomly divided into two groups. In one group, they will receive only routine nursing care, and in the other group, in addition to this care, they will receive care based on a care program taught to nurses. Then the incidence of bedsores and its severity will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria included children 1 month to 6 years old who are candidates for open-heart surgery, no wounds in areas under pressure, and parental consent to participate in the study. Exclusion criteria are a history of skin disease and any allergies; the history of food and drug allergies, hemodynamic instability, and suffering from respiratory distress syndrome.

Intervention groups

In this study, children in the control group will receive only routine nursing care to prevent bedsores. However, children in the intervention group, in addition to routine treatments, are cared for according to the care program taught to nurses.

Main outcome variables

Braden Q Scale score, PUSH score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N12**

Registration date: **2020-11-11, 1399/08/21**

Registration timing: **retrospective**

Last update: **2020-11-11, 1399/08/21**

Update count: **0**

Registration date

2020-11-11, 1399/08/21

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2019-06-22, 1398/04/01

Trial completion date

2019-06-22, 1398/04/01

Scientific title

Evaluation of the effect of a care program on the frequency of occurrence and progression of impaired

skin integrity in one-month to six-year-old children following an open-heart surgery

Public title

Evaluation of the effect of a care program on the progression of impaired skin integrity following an open-heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children who are candidates for open-heart surgery No wounds in the area under pressure of the body Parents' consent for the child's participation in the study Age range 1 month to 6 years

Exclusion criteria:

History of skin disease History of allergies History of food and drug allergies Hemodynamic instability Respiratory Distress Syndrome

Age

From **1 month** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, because in the control group only routine nursing care is provided for the child and in the other group, in addition to routine care, care in accordance with the care program taught to nurses will be performed, so the intervention is performed by awareness. But the child will not be aware of group therapy due to a lack of knowledge about the types of care, and the assessor who comes to collect information about the child in the next follow-up will not be aware of the intervention of the two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Azadi Square.

City

Isfaha

Province

Isfehan

Postal code

8174673461

Approval date

2019-07-09, 1398/04/18

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.227

Health conditions studied

1

Description of health condition studied

congenital heart disease

ICD-10 code

Q24.9

ICD-10 code description

Congenital malformation of heart, unspecified

Primary outcomes

1

Description

PUSH score

Timepoint

The first day and the last day of the intervention

Method of measurement

Pressure Ulcer Scale for Healing (PUSH)

2

Description

Braden Q Scale score

Timepoint

The first day and the last day of the intervention

Method of measurement

Braden Q Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the control group, training is not given to nurses and children are subjected to routine (daily) interventions by nurses, including position change,

moisture management and nutrition. Also, skin protection products are used systematically according to the surgeon in order to prevent and treat skin injuries.

Category

N/A

2**Description**

Intervention group: In the intervention group, child care in the operating room was such that the cotton would be placed on pressure points such as the sacrum, iliac bone, elbow, and back of the child's head to prevent the pressure. Trained by an anesthesiologist every hour during head surgery; The position will be changed while maintaining safe conditions. After surgery, the position will be changed every two hours in bed to prevent abrasion of the scalp and the whole body of children, due to the stability of vital signs. Using a pillow or glove full of water under the heel and small pillows behind the head and between the legs will remove and reduce the amount of pressure. Care and prevention measures will be used using skin protection products such as sprays, foam dressings, and gels.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Chamran Hospital

Full name of responsible person

Ahmadreza Yazdannik

Street address

2nd Moshtagh Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Email

Yazdannik@nm.mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Ahmadreza Yazdannik

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Nursery

Street address

Department of Critical Care Nursing, Chamran
Hospital

City

Isfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Email

Yazdannik@nm.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ahmadreza Yazdannik

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Nursery

Street address

Department of Critical Care Nursing, Chamran
Hospital

City

Isfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Email

Yazdannik@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Malekpour

Position

Nurse

Latest degree

Medical doctor

Other areas of specialty/work

Nursery

Street address

Department of Critical Care Nursing, Chamran
Hospital

City

Isfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Email

Malekpour9880@gmail.com

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 further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available