

# 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.

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8166173414

**Phone**

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**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.

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**Province**

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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**

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**Province**

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**Postal code**

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

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Nursery

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**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**

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**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