

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigation on effect of using air cushion on preventing occipital pressure ulcer of children under heart surgery

Protocol summary

Study aim

To specify the effect of air cushion to prevent occipital pressure ulcer in children under heart surgery

Design

This investigation is done randomly with 126 specimens in control and intrusive group by clinical trial with 2 parallel groups

Settings and conduct

This investigation would be clinical trial that would be done on 126 sick children under open heart surgery referring to Shahid Madani Tabriz and Rajae heart center that have not long hospitalization history in intensive care unit of children. After getting permission from moral committee of medical university of Iran and providing them for medical university of Tabriz and consequently will be given to Shahid Madani and Shahid Rajae heart center, the researcher will start the experimental process. Therefore, the researcher in heart surgery unit, would select children from 0 to 12 years who are candidates of surgery with random and sequence and with getting permission from their parents, will collect data. In addition, the condition of occipital region of their head are observed and will be scored by the Browden checklist.

Participants/Inclusion and exclusion criteria

Children who are 0 to 12 candidates for heart surgery. Those children that go under open heart surgery and this happens via heart and lung pump. conditions of not being accounted: children who are attached to ventilator before heart surgery patients who pass away during the surgery patients who pass away in intensive care unit children whose heart surgery is canceled after anesthesia for any reason

Intervention groups

Intrusive groups: Those groups that by using air cushion prevent occipital pressure ulcer in children control group: Those groups who used conventional method for under head of children

Main outcome variables

Preventing occipital pressure ulcer reduction in duration of hospitalization reduction in costs of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190630044056N1**

Registration date: **2019-08-07, 1398/05/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-07, 1398/05/16**

Update count: **0**

Registration date

2019-08-07, 1398/05/16

Registrant information

Name

Azita Matinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3382 0548

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-07, 1398/04/16

Expected recruitment end date

2019-08-31, 1398/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on effect of using air cushion on preventing occipital pressure ulcer of children under heart surgery

Public title

Investigation on effect of air cushion on preventing occipital pressure ulcer of children

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 0 to 12 candidates for heart surgery. Those Children that go under open heart surgery and this happens via heart and lung pump. Children who diagnosis of their heart illness is confirmed by surgeon and is in queue for heart surgery.

Exclusion criteria:

Children who are attached to ventilator before heart surgery. Patients who pass away during the surgery. Patients who pass away in intensive care unit. Children whose heart surgery is canceled after anesthesia for any reason. Children whose open heart surgery is changed to close one.

Age

From **1 day** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

More than 1 sample in each individual

Number of samples in each individual: **63**

The number of specimens equals to 58 persons and with the possibility of 10% reduction in number of final specimens, are determined 63 persons. The method for calculating number of specimens: for determining number of specimens in meaningful level of 0.05 and power of examination of 80% with considering the 30% pressure ulcer and with the hypothesis that occipital pressure ulcer in children under heart surgery in intrusive group comparing to control group reduces by 20% in order to be considered meaningful in statistical overview.

Randomization (investigator's opinion)

Randomized

Randomization description

The selected qualified specimens, in order to be studied randomly, by using the www.Random.org website and by categorizing with 4 and 6 blocks to 2 groups will be specified. In order to conceal specification, after random sequence by number of specimens, several aluminium envelopes are prepared and cards are placed in envelopes sequential. To preserve random sequence, the envelopes are numbered in order. Finally, the sealed envelope are placed in order into a box. By the time of the registration of the participants, by the considering the the sequence

of qualified participants, they opt for a card and the specified group of this participant will be appeared.

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**

Ethics committee of Iran University of Medical Science

Street address

Iran University of Medical Science, Hemmat highway, Tehran

City

Tehran

Province

Tehran

Postal code

88671613

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.IUMS.REC.1397.373

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

Occipital pressure ulcer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Occipital pressure ulcer incidence

Timepoint

Investigation on incidence of occipital pressure ulcer after surgery up to 3 days in children ICU

Method of measurement

Index of pressure ulcer

2**Description**

Prediction of pressure ulcer score

Timepoint

After surgery in operation room and in children ICU

Method of measurement
Prediction of bradan and bradan q pressure ulcer measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intrusive group: Using air cushion in children under heart surgery in heart operation room and 3 days after heart surgery in children ICU

Category

Prevention

2

Description

Control group: using routine position as cloth rolls or jelly occipital position in children under heart surgery and 3 days after surgery in children ICU

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajae hospital

Full name of responsible person

Azita Matinpour

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakouti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Azita Matinpour

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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