

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigation the effect of physical rehabilitation program's implementation on the physical performance and quality of life rate on hospitalized children undergoing congenital heart disease surgery in intensive care units of chamran hospital in 2019

Protocol summary

Study aim

Investigation the effect of physical rehabilitation program's implementation on the physical performance and quality of life rate on hospitalized children undergoing congenital heart disease surgery in intensive care units

Design

The study is a two-stage clinical trial with two groups. For this purpose, 60 children undergo cardiac surgery. The sampling method will be easy to divide into two groups of intervention and control.

Settings and conduct

The research environment of the pediatric intensive care unit of Shahid Chamran Hospital is affiliated to Isfahan University of Medical Sciences and is followed by a pediatric and then a baby home. In order to carry out research, the researcher will refer to Shahid Chamran Hospital in Isfahan University of medical sciences in order to carry out the research. After describing the objectives and the research process, the collaboration between the hospital and the competent authorities of the pediatric and intensive care units will be sought.

Participants/Inclusion and exclusion criteria

Age range between three and seven years-- Not accompanied by congenital anomaly of the heart with other physical disorders- Exit conditions: The existence of life-threatening arrhythmias- Failure of the physician to continue the rehab program

Intervention groups

Use a routine program for the control group and use a rehab protocol for the intervention group

Main outcome variables

Physical performance , Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190129042547N1**

Registration date: **2019-04-04, 1398/01/15**

Registration timing: **prospective**

Last update: **2019-04-04, 1398/01/15**

Update count: **0**

Registration date

2019-04-04, 1398/01/15

Registrant information

Name

asghar jamshidian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3264 1887

Email address

jamshidian@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Blinding description
Scientific title	Placebo
Investigation the effect of physical rehabilitation program's implementation on the physical performance and quality of life rate on hospitalized children undergoing congenital heart disease surgery in intensive care units of chamran hospital in 2019	Not used
Public title	Assignment
Investigation the effect of physical rehabilitation program's implementation on the physical performance and quality of life on Children undergoing cardiac surgery.	Parallel
Purpose	Other design features
Supportive	The research area of the pediatric intensive care unit of Martyr Dr. Chamran Hospital
Inclusion/Exclusion criteria	Secondary Ids
Inclusion criteria:	empty
- The research unit has no psychiatric disorders or limiting movements - have age limits of between three years of age - The doctor will allow the child to attend the rehab program - Not accompanied by congenital anomaly of the heart with other physical disorders - Failure to implement previous rehab programs on the research unit Research units or parents who would like to participate in this research project - His vital signs are within his normal range - During the procedure, only the parents will take care of the child before surgery until one month later - Their place of residence is Isfahan city and the area where the researcher is able to meet their personal presence. - Ability to make phone calls and stay in touch with the family Children aged 3 to 7 years with congenital heart defects	Ethics committees
Exclusion criteria:	1
Child's death during study - Family unwillingness to continue active participation in the research The presence of threatening arrhythmias - Failure in renal function or other organs of the body Failure of the physician to continue the rehab program	Ethics committee
Age	Name of ethics committee
From 3 years old to 7 years old	Vice- chancellor in research affairs -medical univercity of isfahan
Gender	Street address
Both	Deputy of Research and Technology of the University,Building No. 4,Isfahan University Of Medical Sciences,Heza jerib Ave
Phase	City
N/A	isfahan
Groups that have been masked	Province
No information	Isfahan
Sample size	Postal code
Target sample size: 60	۷۳۴۶۱-۸۱۷۴۶
Randomization (investigator's opinion)	Approval date
Randomized	2019-02-27, 1397/12/08
Randomization description	Ethics committee reference number
Random assignment is used in two groups of random numbers.Using this table, by closing the eyes and by placing a finger on one of the numbers, that number will be selected.The direction to move is predefined and horizontally to the right, then to the top and then to the left of the table.Each number will be placed in group A or intervention, and each pair number will be entered in group B or control.	IR.MUI.RESEARCH.REC.1397.467
Blinding (investigator's opinion)	Health conditions studied
Not blinded	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
	Physical performance
	Timepoint
	Before the intervention and one month after the discharge from the hospital
	Method of measurement
	Early Years Physical Activity Questionnaire
	2
	Description

Quality of life
Timepoint
Before the intervention and one month after the discharge from the hospital
Method of measurement
Paediatric Quality of Life Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of three rehab techniques after the presence of a child in the intensive care unit following cardiac surgery: 1- Kinesitherapy(KTH) 2- Respiratory Physical Therapy 3-Sitting Balance Exercise:This part of the movements, day-after-surgery moves will begin with a balanced baby's condition, which will be held once a day, at least three times a day, and each time it lasts for 20 to 60 minutes.----Program designed for home activity:Postural training-Flexibility training-Breathing training-Muscle strength training-Developmental activities-Aerobic endurance training:These movements will be started in a month and on a daily basis from the time the child is admitted to the pediatric ward and will continue at home.Each session of the program includes 5 to 10 minutes of warm-up, 30 minutes of aerobic exercise, with a low to moderate intensity and 5 minutes of cooling down.

Category

Rehabilitation

2

Description

Control group: For the control group, the routine of the child care and care units and the protocol that the hospital has implemented so far will be used, including providing family descriptions of physical rehab programs in verbal conversation and answering their questions in this regard And offering educational pamphlets.For the investigated families, a classroom session is organized individually and grouply, at the beginning of the course.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Chamran hospital
Full name of responsible person
Jamshidian Asghar
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Haghjooe Javanmard Shaghaiegh
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Deputy of Research and Technology of the University,Building No. 4,Isfahan University Of Medical Sciences,Heza jerib Ave
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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

Esfahan 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

Khalifezadeh Asghar

Position

Academic Member In Isfahan University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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