

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

A Comparative Study on the Effect of two Methods of Preoperational preparation; Hospital Tours and Oral Presentation, on the Anxiety of Mothers before Open Heart Surgery for Children with Congenital Heart Disease

Protocol summary

Study aim

Determining and comparing the effect of preoperative preparation on oral presentation and hospital tour on the anxiety of mothers before the open heart surgery of a child with congenital heart disease hospitalized in pediatric cardiac ward of Shahid Modarres Hospital in Tehran

Design

Clinical trial, one-blind, randomized control group

Settings and conduct

Research environment is Children's Heart Department of Shahid Modares Hospital. Mothers with children aged 1 to 3 years with a diagnosis of congenital heart disease candidates for open heart surgery are selected using available sampling method. mothers were randomly assigned to each group: Oral Preparation, Hospital Tour Preparation, and Standard preparation group, sampling in each group takes place within a week to prevent the association of mothers in the three groups.

Participants/Inclusion and exclusion criteria

Have reading and writing skills and ability to speak Persian, Mother's age is 20 to 50 years old Exit criteria: Cancel surgery, Child's death, Exacerbation of the child's disease, Mother's departure

Intervention groups

In the oral explanation group, between 8:00 (Am) and 10:00 (Am) at morning and between 4-6 evenings in the afternoon session, the mothers participated in oral explanation sessions for 30 to 45 minutes. In the hospital tour group, two 30-45 minute rotations in the morning and evening to the operating room and the ICU section are carried out by a researcher with the participating mothers and the same explanations are given. In the Standard group, mothers do not receive any training by the researcher

Main outcome variables

Helping mothers of children born with congenital heart disease to reduce their anxiety during Open Heart surgery of their children is the result of this research.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190130042557N1**

Registration date: **2019-04-17, 1398/01/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-17, 1398/01/28**

Update count: **0**

Registration date

2019-04-17, 1398/01/28

Registrant information

Name

Asal Amintojari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2676 3815

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a.amintojari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study on the Effect of two Methods of Preoperational preparation; Hospital Tours and Oral Presentation, on the Anxiety of Mothers before Open Heart Surgery for Children with Congenital Heart Disease

Public title

Comparison of the Effect of Oral Presentation and Hospital Tour on Mothers' Anxiety before the Children's Open Heart Surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All mothers of children with congenital heart disease who are admitted to open heart surgery The mother is fluent in reading and writing and speaking in Persian The mother is not afflicted with mental and anxiety disorders Mother does not have a child with a history of heart surgery Mother has no education in medical sciences and psychology Mother is married Mother has a biological relationship with the child

Exclusion criteria:

A child is at the age of infancy, young child, or school age. Mother is illiterate. The mother has anxiety or mental disorders. Single mother The child is admitted to the pediatric department of the Modares Hospital for angiography.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The Mothers are selected using the available sampling method(In each three-week round, it is determined by simple drawings, which groups of participants in each week are placed in each of the three groups, and in order to prevent the association of mothers, sampling in each group takes place within a week) and gradually and in a simple randomized manner, they are placed in three groups: Oral presentation preparation, Hospital tour preparation and Standardized preparation.Sampling continues continuously until the required sample size is completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind study and participants are unaware of the allocation of study groups. After obtaining informed consent from Mothers, in each three-week period, it is determined by a simple draw that each participant in each of the three study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti Faculty of Nursing and Midwif,Valiasr Intersectionery, Niyayesh Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-05-01, 1395/02/12

Ethics committee reference number

IR.SBMU.PHNM.1395.683

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

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Mother anxiety in the Spielberg and Amsterdam questionnaires

Timepoint

Determine the anxiety level of the day before surgery (before intervention) and one hour before surgery (after surgery)

Method of measurement

In the study "Comparative study of the effect of

preoperative preparation in two ways; Hospital tour and oral explanation on the anxiety of mothers before open heart surgery for children with congenital heart disease", the variable measurement method can be "Amsterdam Preoperative Anxiety and Information Scale" And the "spielberger state trait anxiety inventory" questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention group: Mothers receive oral information in two sessions in the morning and evening of preoperative preparation.

Category

Behavior

2

Description

Intervention group: Second intervention group: Mothers receive Hospital Tour preparation information in two sessions in the morning and evening.

Category

Behavior

3

Description

Control group: This group does not receive any interventions by the researcher and only receive routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Asal Amin Altojari

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Kaj Square, Saadat Abad Street

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modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Manizhe Nouriyar

Street address

Modarres Hospital, Kaj Square, Saadat Abad

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Asal Amin Altojari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about participants is shared without their identification.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers and people working at the clinic and hospital

Under which criteria data/document could be used

Information is available to individuals when using research results in a hospital and implementing research methods.

From where data/document is obtainable

Email a.amintojar@gmail.com to receive the data.

What processes are involved for a request to access data/document

After receiving the email from the person requesting the information, information is sent after 1 to 2 weeks.

Comments