

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation The Effect of Mother's Recorded Voice Compared To Routine Care on Pain Intensity and Physiological Indicators in Children Undergoing Surgery for Congenital Heart Disease

Protocol summary

Study aim

To Determine the Effect of Mother's Recorded Voice on Pain Intensity and Physiological Indicators in Children Undergoing Surgery for Congenital Heart Disease.

Design

Phase III randomized clinical trial with two groups, without blinding, consisted of 72 people, random allocation through PASS 11 software.

Settings and conduct

The location of the study is open heart ICU of Imam Reza Hospital in Mashhad. The study population is children undergoing surgery for congenital heart disease. Blinding is not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: the Age of the Child is Between 2 Months and 5 Years and the Child is Undergoing Surgery for Congenital Heart Disease. Exclusion Criteria: Having Neurogenic Developmental Disorders; Hearing Impairment; Previous Surgical History

Intervention groups

In the intervention group, the researcher records the mother's voice (including free conversation with the child or her favorite poems). After the end of the surgery, in addition to the drugs used, the recorded voice is played when the child enters the open heart ICU and then every two hours up to 6 hours and then every four hours up to 24 hours (or until the mother's presence in the ICU). Routine drugs will be used in the control group.

Main outcome variables

Pain intensity; physiological indicators.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231014059712N1**

Registration date: **2023-11-12, 1402/08/21**

Registration timing: **prospective**

Last update: **2023-11-12, 1402/08/21**

Update count: **0**

Registration date

2023-11-12, 1402/08/21

Registrant information

Name

Zahra Sadegh al-Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3606 8913

Email address

sadeghhz992@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-13, 1402/08/22

Expected recruitment end date

2024-03-12, 1402/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation The Effect of Mother's Recorded Voice Compared To Routine Care on Pain Intensity and Physiological Indicators in Children Undergoing Surgery for Congenital Heart Disease

Public title

The Effect of Mother's Recorded Voice on Pain Intensity And Vital Signs of Children Undergoing Surgery for Congenital Heart Disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Mother's Consent to Participate in the Research Child Undergoing Surgery for Congenital Heart Disease The Age of the Child is Between 2 Months and 5 Years

Exclusion criteria:

Having Neurogenic Developmental Disorders Hearing Impairment Previous Surgical History

Age

From **1 month** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done in such a way that people will be divided into two groups through the PASS 11 software using blocks of size four. In this way, after determining the sequence, we put them in the envelopes and number them in order. Mothers take the envelope in the order of their entry into the study and are placed in the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Regarding the method of recording the voice, it is explained to the mother that her voice will be recorded at a time of the day in the rooms of the department (open heart surgery in Imam Reza Hospital) which is quiet and appropriate. In this way, the mother is asked to express the words and sentences she uses to calm her child. Audio content can include free conversations with the child or the child's favorite poems. The mother's voice is recorded by the researcher using a mobile recorder for 5 minutes. Then, on the next day, after the end of the surgery, the sound recorded using the researcher's mobile phone is played next to the child's ear at several time points: first, when the child enters the open heart ICU, and then every two hours until 6 hour and then every four hours until 24 hours (or until the mother is in the ICU). Measurement of pain level and physiological indicators (heart rate, breathing, systolic/diastolic blood pressure, SPO2) first at the time of entering the ICU (baseline data), then before the start of each intervention and also 15 minutes after each time

playing the sound with FLACC (Face, Legs, Activity, Crying and Consolation) modified behavioral scale of pain is used and the values of physiological indicators are measured and recorded in the relevant form using the monitoring available in the open heart ICU.

Secondary Ids

empty

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

Ethics Committee of Faculty of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address

Educational Complex of Shahid Dr. Kharazmi, University Campus, east gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2023-08-15, 1402/05/24

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.079

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

Children undergoing surgery for congenital heart disease

ICD-10 code

Q20

ICD-10 code description

Congenital malformations of cardiac chambers and connections

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

Intensity of Pain

Timepoint

Pain Intensity is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played.

Method of measurement

FLACC Modified Behavioral Pain Scale (Face, Legs, Activity, Cry, Consolability)

2

Description

Heart Rate

Timepoint

Heart Rate is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.

Method of measurement

This variable is recorded as number per minute (heart rate and breathing) using "SADAT" Cardiac Monitoring Device.

3

Description

Respiration

Timepoint

Respiration is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.

Method of measurement

This variable is recorded as numbers per minute using the "SADAT" Cardiac Monitoring device.

4

Description

Systolic/Diastolic Blood Pressure

Timepoint

Systolic/Diastolic Blood Pressure is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.

Method of measurement

This variable is measured and recorded by the Oscillometric Method by tying the Sphygmomanometer Cuff to the child's arm using a Cardiac Monitoring Device, and its unit is Millimeters of Mercury.

5

Description

Oxygen saturation (SpO2)

Timepoint

SPO2 is Measured at the Time of Entering the ICU (Baseline Data), Before the Start of each Intervention and also 15 Minutes after each Time the Mother's Voice is Played Using the Monitoring Device in the Ward.

Method of measurement

This variable is controlled and recorded by connecting the Pulse Oximetry Probe to the child's leg by a Heart Monitoring Device, which is shown as a Percentage.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group, in addition to the routine medical treatment, the mother's recorded voice next to the child's ear using a mobile phone, when the child entered the open-heart ICU, and then every two hours up to 6 hours, and then every four hours. It is played for up to 24 hours (or until the mother is in the ICU). The level of pain and physiological indicators (heart rate, respiration, systolic/diastolic blood pressure, SaO2) at the time of admission to the ICU (baseline data), before the start of each intervention and also 15 minutes after each time playing the sound using a behavioral scale. Adjusted pain FLACC (face, legs, activity, crying and consolation) is measured and the values of physiological indicators are measured using the monitoring available in the open heart ICU department and recorded in the relevant form.

Category

Treatment - Other

2

Description

Control group: In this group, the usual care, which includes routine drug therapy, is performed. These drugs include Dexmedetomidine: 0.2-0.5 mcg/kg/h, Fentanyl: 2-0.5 mcg/kg/h, Midazolam: 0.5 mcg/kg/min, Ceftazidime: 30-50 mg/kg q8h, Vancomycin: 10mg/kg, Magnesium Sulfate: 15-50mg/kg q4-6h, Potassium Chloride: 0.5meq/kg/h, every 12 hours. Pain scale and physiological indicators are measured at the same time as the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Open Heart ICU; Imam Reza Hospital

Full name of responsible person

Zahra Dalir

Street address

Imam Reza Educational Research and Treatment Center, Imam Reza Hospital Square, Ibn Sina Ave, Mashhad, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

dalirz@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Research and Technology Vice-Chancellor of Mashhad University of Medical Sciences, Second Floor, Qureshi Building, in front of Daneshgah 16 Ave, Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

tafaghodim@mums.ac.ir

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Dalir

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Educational Complex of Shahid Dr. Kharazmi, University Campus, east gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

dalirz@mums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Sadegh al-Hosseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 57, Soroush 11, Farhang 10, Farhang Blvd., Jalal Al-Ahmad

City

Mashhad

Province

Razavi Khorasan

Postal code

9188875816

Phone

+98 51 3606 8913

Fax**Email**

sadeghhz992@mums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Sadegh al-Hosseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 57, Soroush 11, Farhang 10, Farhang Blvd., Jalal Al-Ahmad

City

Mashhad

Province

Razavi Khorasan

Postal code

9188875816

Phone

+98 51 3606 8913

Fax

Email

sadeghhz992@mums.ac.ir

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

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

Title and more details about the data/document

All the data obtained from this research will be shared after completion.

When the data will become available and for how long

Access to the data will be possible 3 months after the results are published.

To whom data/document is available

These data will be used for researchers working in academic and scientific institutions, as well as for parents with children with congenital heart disease.

Under which criteria data/document could be used

The data obtained from this research can be used in other scientific studies.

From where data/document is obtainable

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

The applicant should send an email to the responsible author and register his request. After verifying the correctness of the information of the mentioned person, the required content will be provided to him by mentioning the source.

Comments