

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

the effect of mothers voice on arterial blood sampling on pain and physiological indicators in peditrics hospitalized in pediatric intensive care unit

Protocol summary

Study aim

Effect of Mother Recorded Voice on Pain and Physiological Criteria During Arterial Blood Sampling in Pediatric Patients

Design

Participants will be selected in sequential method. they enter in two groups(A, B) with random allocation with 2 blocking . Group A: Getting arterial blood sampling while listening to mother's voice.and then Getting arterial blood sampling without listening to mother's voice Group A: Getting arterial blood sampling without listening to mother's voice and then Getting arterial blood sampling while listening to mother's voice.

Settings and conduct

The study will be cross-over. Participants will be divided into two groups A and B based on the 2 blocking method. In group A, blood sampling will be performed first listening of the mother's voice and then without the listening of mother's voice. In group B, blood sampling will be done first without the listening of mother's voice and then with the listening of mother's voice. In both groups the headphones will be on the child's ear and the pain assessment will be done without knowing the status of the mother's listening or not. The data will be analyzed in the form of code and without information about the order of intervention.

Participants/Inclusion and exclusion criteria

Have at least 9 alertness levels based on Glasgow scale
No have hearing impairment
No be under ventilation
Do not take analgesic drugs at least three hours before sampling
No have developmental delay
No have cognitive disorders
No have neuromuscular disorders, including guillain barre and mental retardation

Intervention groups

Listening to mother's voice during arterial blood sampling

Main outcome variables

Pain and physiological criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N6**

Registration date: **2019-09-22, 1398/06/31**

Registration timing: **retrospective**

Last update: **2019-09-22, 1398/06/31**

Update count: **0**

Registration date

2019-09-22, 1398/06/31

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4687 1192

Email address

shoghi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-28, 1397/11/08

Expected recruitment end date

2019-03-28, 1398/01/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
the effect of mothers voice on arterial blood sampling on pain and physiological indicators in pediatrics hospitalized in pediatric intensive care unit

Public title
The effect of mothers voice on Pain and physiological indicators during arterial blood sampling and in children hospitalized in pediatric intensive care unit

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Have at least 9 alertness levels based on Glasgow scale
No have hearing impairment
No be under ventilation
No take analgesic drugs at least three hours before sampling
Lack of childhood developmental delay
No have cognitive disorders
No have Neuromuscular disorders, such as Guillain Barre and mental retardation
Exclusion criteria:

Age
From **2 years** old to **8 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **100**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each child's pain is evaluated at an early stage by listening to the mother's voice during arterial blood collection and one more time without listening to the mother's voice during arterial blood transfusion.

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling will do in sequential method. random allocation will used with 2 blocking. The participants will be divided into two groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Research assistance during the process of data gathering. will not know that The child listen to mother voice or not. Data will be sent in coding (A,B) for analysis.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran, Valiasr Ave., higher than Vanak Square, Rashidiassemi Avenue, Iran Nursing Midwifery Faculty

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2018-12-23, 1397/10/02

Ethics committee reference number

IR.IUMS.REC.1397.701

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Physiologic indicators

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain during arterial blood sampling

Timepoint

Before arterial blood sampling, during arterial blood sampling

Method of measurement

pain assessment comfort scale

2

Description

physiological indicators

Timepoint

Before arterial blood sampling, during arterial blood sampling

Method of measurement

Record from monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Getting arterial blood sampling while the child listen to mother's voice and after at least 24 hours getting arterial blood sampling while the child don't listen to mother's voice. pain and physiologic indicators will be assessed before and during arterial blood sampling

Category

Other

2

Description

Intervention group B: Getting arterial blood sampling while the child don't listen to mother's voice. and after at least 24 hours getting arterial blood sampling while the child listen to mother's voice. pain and physiologic indicators will be assessed before and during arterial blood sampling

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Ms. Azam Abbasi

Street address

Sattar Khan Street. Niyayesh Street. Rasoul-e-Akram

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seid Kazam Malakuti

Street address

School of Nursing and Midwifery, Shahid Yasemi Street., North Kordestan Highway., Tehran., IRA

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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

Mahnaz Shoghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

Nursery

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After Data coding in order to keep the confidentiality of the participants in the research.

When the data will become available and for how long

The end of sampling till six months after article publishing.

To whom data/document is available

Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used

Systematic review and meta-analysis or secondary analysis citation

From where data/document is obtainable

Mahnaz Shoghi, Email: shoghi.m@iums.ac.ir

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

After sending a request to academic email, we will send our data files up to one week.

Comments