

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of mother's recorded voice on the severity of pain and anxiety in pediatric undergoing surgery

Protocol summary

Study aim

Determining the Effect of Mother Recorded Voice on the Severity of Pain and Anxiety in Pediatric Patients
Admitted to the Hospital of Ali ibn Abitaleb Zahedan in 2019

Design

Clinical trials with control group; randomized, community-based and practical, with parallel groups without blinding.

Settings and conduct

Children undergoing abdominal surgery in Ali ibn Abi Talib Hospital are randomly divided into two groups, and the voice of the mother is recorded on the day before the operation and is distributed to the child in two stages with headphones played. preoperative anxiety And the pain is after surgery measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Surgery in the lower abdomen; The child's desire to hear the voice of the mother; Non-emergency surgery; Anesthesia (general anesthetic) and surgery protocols are the same; Mother's presence. Non-inclusion criteria: The occurrence of specific problems during surgery (bleeding beyond the limit, re-intubation of the trachea); Having long-lasting illness in the last 3 months; Having a history of surgery within last year; Presence of hyperactivity disorder or other mental disorders (according to the patient's history); Hearing disorder.

Intervention groups

Intervention group: The mother's voice is played in two stages. The first stage is to reduce preoperative anxiety and the second stage is used to reduce postoperative pain. The sound content includes poetry or speech, related to the request of the child. In the control group, the headphones are connected to the silent device on the child's ear.

Main outcome variables

Anxiety; the amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041960N1**

Registration date: **2019-02-06, 1397/11/17**

Registration timing: **prospective**

Last update: **2019-02-06, 1397/11/17**

Update count: **0**

Registration date

2019-02-06, 1397/11/17

Registrant information

Name

Fateme Avizhgan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4487 3295

Email address

avizhgan_f@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mother's recorded voice on the severity of pain and anxiety in pediatric undergoing surgery		Zahedan
Public title		Province
The effect of mother's voice on the pain and anxiety of children		Sistan-va-Balouchestan
Purpose		Postal code
Supportive		9816743463
Inclusion/Exclusion criteria		Approval date
Inclusion criteria:		2018-12-02, 1397/09/11
Surgery in the lower abdomen The child's desire to hear the voice of the mother Non-emergency surgery Anesthesia (general anesthetic) and surgery protocols are the same Mother's presence		Ethics committee reference number
Exclusion criteria:		IR.ZAUMS.REC.1397.342
The occurrence of specific problems during surgery (bleeding beyond the limit, re-intubation of the trachea) Having long-lasting illness in the last 3 months Having a history of surgery within last year Presence of hyperactivity disorder or other mental disorders (according to the patient's history) Hearing disorder		Health conditions studied
Age		1
From 3 years old to 6 years old		Description of health condition studied
Gender		Preoperative anxiety
Both		ICD-10 code
Phase		F41.1
N/A		ICD-10 code description
Groups that have been masked		Generalized anxiety disorder
No information		2
Sample size		Description of health condition studied
Target sample size: 80		Pain Acute
Randomization (investigator's opinion)		ICD-10 code
Randomized		R52.0
Randomization description		ICD-10 code description
Envelopes containing cards with numbers one and two are given to the participants, if the number one is chosen, they will be assigned to the intervention group. Otherwise they will be assigned to the control group.		Pain, Acute
Blinding (investigator's opinion)		Primary outcomes
Not blinded		1
Blinding description		Description
Placebo		pain
Not used		Timepoint
Assignment		Half an hour , 1 hour after surgery
Parallel		Method of measurement
Other design features		Pediatric Pain Inventory Scale,, Ouscher Self Report Questionnaire
Secondary Ids		2
empty		Description
Ethics committees		Anxiety
1		Timepoint
Ethics committee		On entering the operating room and 15 minutes after the intervention
Name of ethics committee		Method of measurement
Ethics committee Zahedan University of Medical Sciences and Health Services		Modified- Yale preoperative anxiety scale
Street address		Secondary outcomes
Zahedan University of Medical Sciences, Janat Blvd		empty
City		Intervention groups
		1
		Description
		Intervention group: Mother's voice is used in two stages.

The first stage was to reduce the anxiety before surgery and the second time to reduce postoperative pain. According to the request of the child or his mother, the content of the sound includes poetry or regular speech to reduce the child's anxiety. In the second step, the mother is given a written text that she will read it to reduce the pain after surgery.

Category

Rehabilitation

2**Description**

Control group: The headphones connected to the silent device are placed on the child's ear.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Abne Abitaleb Hospital affiliated to Zahedan University of Medical Sciences and Health Services

Full name of responsible person

Fateme Avizhgan

Street address

Zahedan University of Medical Sciences, Janat Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5796

Email

avizhgan.sara73@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Normohammad Bakhshany

Street address

Zahedan University of Medical Sciences, Janat Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5796

Fax**Email**

avizhgan.sara73@gmail.com

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

Yes

Title of funding source

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Avizhgan

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery Faculty, Behdasht Blvd,

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2481

Email

avizhgan.sara73@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Avizhgan

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Zahedan Nursing and Midwifery Faculty, Behbasht

blvd
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816913396
Phone
+98 54 3344 2481
Email
avizhgan.sara73@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Fateme Avizhgan
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Behdaht blvd,
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
9816913396
Phone
+98 54 3344 2481
Email
avizhgan.sara73@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

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