Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative Study of the Effect of maternal voice and midazolam on anxiety, Blood Pressure and Heart Rate in pediatric patients undergoing surgery

Protocol summary

Study aim

Determining the effect of maternal midazolam voice on anxiety, blood pressure and heart rate in sick children Candidate for surgery in the operating room

Design

The first patient referred to the candidate to be randomly assigned to participate in the study is assigned to one of the control and control groups, and the next patients are assigned to the control and control group alternately, thus forming 30 people in each group.

Settings and conduct

Sample size was determined by considering 5% alpha, 20% beta,standard deviation of 6 in two groups and the difference between the mean of children's anxiety based on behavior at 5 in each group of 27 people, which considering 10%fall, finally 30 people Sampling will be done in each group.The first patient referred to the candidate to be randomly assigned to participate in the study is assigned to one of the control and control groups, and the next patients are assigned to the control and control group alternately, thus forming 30people in each group.

Participants/Inclusion and exclusion criteria

Conscious consent of parents of patients, having an age of 2 to 8 years for pediatric patients, candidate for elective surgery

Intervention groups

GroupM includes oral midazolam about half an hour before surgery at a dose of 0.5 mg per kilogram of body weight with 20cc of water, and groupV includes the mother's voice, which is recorded on a mobile phone using smart Voice Recorder 1.7 software. In this study, the purpose of playing the recorded voice of the mother is to talk to the child according to the child's habit. Playing the mother's voice for the child from the time the child separates from the parents until the start of the surgery is a normal conversation with the child. It should be noted that the duration of this Voice is between 10 and 15 minutes.

Main outcome variables

Anxiety, blood pressure, heart rate, arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047226N2**
Registration date: **2020-07-24, 1399/05/03**
Registration timing: **prospective**

Last update: **2020-07-24, 1399/05/03**
Update count: **0**

Registration date

2020-07-24, 1399/05/03

Registrant information

Name

ehsan memarbashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3272 4978

Email address

ehsan.memar1991@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Study of the Effect of maternal voice and midazolam on anxiety, Blood Pressure and Heart Rate in pediatric patients undergoing surgery

Public title
Comparative Study of the Effect of maternal voice and midazolam on anxiety, Blood Pressure and Heart Rate in pediatric patients undergoing surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients should be at least 2 years old and at most 8 years old Patients are referred to the operating room for elective surgery Having a specific parent or guardian at the time of admission
Exclusion criteria:
Have no underlying disease and no history of surgery. Have no history of taking sedatives. The patient has no airway problems. The patient's surgery is not emergency.
Age
From **2 years** old to **8 years** old
Gender
Both

Phase
2
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The first patient referred as a candidate to participate in the study is randomly assigned to one of the case and control groups, and the next patients are alternately assigned to the case and control groups, so that each group consists of 30 people. However, the person in charge of collecting samples in the operating room is unaware of the type of intervention for the patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Teacher Street. Teacher's Square Deputy of Research
City
sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Approval date
2020-05-02, 1399/02/13
Ethics committee reference number
IR.MAZUMS.REC.1399.147

Health conditions studied

1

Description of health condition studied
Tonsillectomy surgery
ICD-10 code
J03.0
ICD-10 code description
Streptococcal tonsillitis

Primary outcomes

1

Description
Anxiety
Timepoint
Patient admission time in the operating room
Method of measurement
(Modified-Yale preoperative anxiety scale

2

Description
blood pressure
Timepoint
During intubation, 5 and 10 minutes after anesthesia and during recovery
Method of measurement
View patient monitor

3

Description
heart rate
Timepoint

During intubation, 5 and 10 minutes after anesthesia and during recovery

Method of measurement

View patient monitor

4

Description

Arterial oxygen saturation

Timepoint

During intubation, 5 and 10 minutes after anesthesia and during recovery

Method of measurement

View patient monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group V includes the mother's voice, which is recorded on the mobile phone using smart Voice Recorder 1.7 software. In this study, the purpose is to play the recorded voice of the mother by talking to the child according to the child's habit. Playing the mother's voice for the child from the time the child separates from the parents until the start of the surgery is a normal conversation with the child. It should be noted that the duration of this Voice is between 10 and 15 minutes.

Category

Behavior

2

Description

Control group: Group M consists of oral midazolam about half an hour before surgery at a dose of 0.5 mg per kg body weight with 20 cc of water.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali

Full name of responsible person

Ehsan Memarbashi

Street address

Mazandaran - Pasdaran Boulevard - Bu Ali Sina Medical Training Center

City

Sari

Province

Mazandaran

Postal code

17117

Phone

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Email

Booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Nasiri Fermi

Street address

Sari, 18 km of Khazarabad Road, University Complex of the Great Prophet (PBUH)

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 56 3272 4978

Email

Ebrahim.Nasiri.f@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

70

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

Mazandaran University of Medical Sciences

Full name of responsible person

Memarbashi

Position

operation room

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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ehsan.memar1991@gmail.com

Person responsible for scientific inquiries

Contact
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Mazandaran University of Medical Sciences
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Other areas of specialty/work
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
In this study, individuals' data information is provided in a confidential manner, which is provided by individuals in the study without names and details to better present the article.
When the data will become available and for how long
Until the publication of the article of this fact sheet
To whom data/document is available
People who collaborate in this study.
Under which criteria data/document could be used
To analyze data to achieve P Value
From where data/document is obtainable
To colleagues in studies and journals
What processes are involved for a request to access data/document
The result of the research can be sent to the applicants via email.
Comments