

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Investigating the effect of showing educational videos On the level of anxiety of mothers referred to preoperative anesthesia clinic

Protocol summary

Investigating the effect of showing educational videos on the level of anxiety of mothers of patients

Study aim

determining the effect of showing educational videos On the level of anxiety of mothers referred to preoperative anesthesia clinic

Design

Clinical trial with control group, With parallel groups, double blinded that the patient and the person completing the questionnaires are unaware of the intervention. Randomization is depending on the clinic's number of shifts given to each patient, Couples are in the control group and the individual numbers are in the intervention group.

Settings and conduct

This study will be performed on the mothers of patients referred to the anesthesia clinic of the Children's Medical Center Hospital. The demographic checklist is completed for everyone and then an instructional video will be shown for the intervention group. After the pre-anesthesia visit, the level of anxiety in both groups will be measured by 21 Beck Anxiety questionnaire.

Participants/Inclusion and exclusion criteria

inclusion criteria is the mothers of all the patients will be referred to the anesthesia clinic of the medical center hospital for a preoperative visit. The ability to speak and understand Persian fluently, ability to take care of yourself and your baby, lack of mental and physical illness and be literate. the exclusion criteria include history of abortion in the mother Physical and mental problems in the child (mental retardation, cerebral palsy and chronic congenital defects) Incurable disease of the child.

Intervention groups

En In this study, randomization by odd even and odd numbers and showing videos to members of the intervention group was done by general Practitioner in the waiting room. Analysis of questionnaires of the intervention and control group was performed by anesthesiologist.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047530N1**

Registration date: **2020-07-15, 1399/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-15, 1399/04/25**

Update count: **0**

Registration date

2020-07-15, 1399/04/25

Registrant information

Name

Nima Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 2569

Email address

n-nazari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of showing educational videos On the level of anxiety of mothers referred to preoperative anesthesia clinic

Public title

Investigating the effect of showing educational videos On the level of mothers anxiety

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

The mothers of all the patients will be referred to the anesthesia clinic of the medical center hospital for a preoperative visit. The ability to speak and understand Persian fluently, ability to take care of yourself and your baby, lack of mental and physical illness and be literate

Exclusion criteria:

the exclusion criteria include history of abortion in the mother Physical and mental problems in the child (mental retardation, cerebral palsy and chronic congenital defects) Incurable disease of the child

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization by odd even and odd numbers and showing videos to members of the intervention group was done by general Practitioner in the waiting room.

Blinding (investigator's opinion)

Double blinded

Blinding description

For this study, blinding will be done as a two blind study. Dividing the participants into two groups and showing the video was done by the medical student and evaluation of all participants was done by an anesthesiologist. Participants did not know how the intervention worked and the anesthesiologist (evaluator) does not know which client the film is shown to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Qods st

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-05-21, 1399/03/01

Ethics committee reference number

IR.TUMS.CHMC.REC.1399.025

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

mother's anxiety

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety score in Beck questionnaire

Timepoint

Anxiety measurement when visiting a pre-anesthesia clinic

Method of measurement

Beck Anxiety Questionnaire

Secondary outcomes**1****Description**

Beck's questionnaire anxiety score

Timepoint

Measuring the Beck Anxiety Score when the patient's mother enters the anesthesia clinic

Method of measurement

Questionnaire 21 Beck Anxiety Questions

Intervention groups

1

Description

Intervention group: Show the instructional video of about 5 minutes prepared by the researcher herself including the preoperative sedation process,taking IV under inhalation induction, then general sedation or anesthesia, and recovery phase

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Childrens Medical Center Hospital

Full name of responsible person

Dr. Nima Nazari

Street address

Dr. Gharib st, Childrens Medical Center Hospital

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1419733151

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cmcpr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Nima Nazari

Position

assistant professor, anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The checklist and anxiety questionnaire of the subjects studied can be shared.

When the data will become available and for how long

Access starts 6 months after printing the results.

To whom data/document is available

The data will be available to researchers working at academic and scientific institutions.

Under which criteria data/document could be used

Data if needed, after correspondence and announcement of the cause of the need, the data will be made available to them.

From where data/document is obtainable

Dr. Nima Nazari Childrens Medical Center Hospital
00982161472569 nima.nazari1366@gmail.com

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

The request will be sent to the respondent's e-mail and the documents will be submitted within 5 working days.

Comments