

# 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

**City**

Tehran

**Province**

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**Postal code**

1419733151

**Phone**

+98 21 6147 2569

**Email**

cmcpr@tums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Nima Nazari

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vcr@tums.ac.ir

**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**

**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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Nima Nazari

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assistant professor, Anesthesiologist

**Latest degree**

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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**