

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jul 2026

### The effect of preoperative preparation program with different method and time on anxiety of school-age children and parents: factorial design

#### Protocol summary

##### Summary

This study is a clinical trial 2×2 factorial design. Factors studied method and time of preoperative preparation program. The aim of this study compare the effect of preoperative preparation program with different method and time on anxiety of school age children and their parents. Inclusion criteria include: "The children ranged from 6 to 12 years"; "pediatric surgery as apply on day care unit (hospitalization up to 1 day"; "Speech, vision and hearing well"; "do not have psychological disease"; "children are not single parent"; "children did not have surgery before"; "surgery is elective"; "parents are not hospital staff. Exclusion criteria: "surgery to be canceled"; "the patient does not refer to hospital for surgery on the day of surgery"; "polygraph questionnaire scores Children's Manifest Anxiety Scale more than 20%"; "unwillingness children and their parents at each stage of research. Sampling was non-probability available, distributed in four groups will be randomly. In the first group after doctor's visit, educational film displayed with descriptions nurse. The second group only educational film displayed without nurse. In the third group on the morning of the surgery day educational film displayed with descriptions nurse. In fourth group on the morning of the surgery day only educational film displayed. To measure the level of anxiety in children of Children's Manifest Anxiety Scale (RCMAS) and anxiety for parents was used Spielberger state-trait anxiety inventory (STAI) on two occasions, first time before the intervention and the second time before entering the operating room was completed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016091829798N2**

Registration date: **2016-12-27, 1395/10/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-27, 1395/10/07

##### Registrant information

###### Name

Malihe Shoja

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 915 520 0415

###### Email address

shojam2@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2016-11-20, 1395/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of preoperative preparation program with different method and time on anxiety of school-age children and parents: factorial design

##### Public title

The effect of preoperative preparation program on anxiety of school-age children and parents

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria include: "The children ranged from 6 to 12 years"; "pediatric surgery as apply on day care unit (hospitalization up to 1 day"; "Speech, vision and hearing well"; "do not have psychological disease"; "children are not single parent"; "children did not have surgery before"; "surgery is elective"; "parents are not hospital staff. Exclusion criteria: "surgery to be canceled"; "the patient does not refer to hospital for surgery on the day of surgery"; "polygraph questionnaire scores Children's Manifest Anxiety Scale more than 20%"; "unwillingness children and their parents at each stage of research.

## Age

From **6 years** old to **12 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **96**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Factorial

## Other design features

In this study, preoperative preparation program consists of training that is provided with educational videos, interviews, questions and answers for sick children and their parents. Training video is 8 minutes and includes all steps that will follow children from the time of referral to admission, enter the surgical ward and admission, preparing children for surgery include change dressing, transfer to the operation room and anesthesia and then the recovery, meet their parents, transfer to ward. The program was conducted in two methods with or without explanations nurse and two different times before and the day of surgery. Training was teaching team and each groups had 3-5 members. Sampling is available and non-probability, then were randomly distributed in to 4 groups. Allocation of sample in to different groups was stratified block. Based on the patient training in ward or clinic were divided into two classes, then for each class separately using a random list of four blocks. In this method, showing educational film with description nurse with A and showing educational film without description nurse with B. Block quadruple meaning that of every four patients. Two patients are in A, two patients are in B.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences.

##### Street address

Knowledge and Health City – In the end of Shahid Fakouri Blvd. – Mashhad - Iran

##### City

Mashhad

##### Postal code

99191-91778

##### Approval date

2016-06-01, 1395/03/12

##### Ethics committee reference number

IR.MUMS.REC.1395.122

## Health conditions studied

### 1

#### Description of health condition studied

anxiety

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Anxiety in children and their parents

#### Timepoint

Assess the level of anxiety of children and their parents in two occasions, the first time before training and watching film and the second time before admission children in the operating room.

#### Method of measurement

Using the RCMAS in children and Spielbergerfor in parents

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention1. In the clinic and after doctor's visits, educational film displayed with descriptions nurse and after viewing the film was answered questions from children and parents.

#### Category

Behavior

## 2

### Description

Intervention4. In the morning of the surgery day only educational film displayed without nurse.

### Category

Behavior

## 3

### Description

Intervention2. In the clinic and after doctor's visits, educational film displayed without nurse.

### Category

Behavior

## 4

### Description

Intervention3. In the morning of surgery day educational film displayed with descriptions nurse and after viewing the film was answered questions from children and parents.

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Doctor Sheikh Hospital

#### Full name of responsible person

Malihe Shoja

#### Street address

Doctor Sheikh street

#### City

Mashhad

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

#### Full name of responsible person

Doctor Saeed Eslami

#### Street address

University St., Ghorashy Building

#### City

Mashhad

#### Grant name

#### Grant code / Reference number

941519

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

Yes

#### Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Malihe Shoja

#### Position

MSC of Nursing

#### Other areas of specialty/work

#### Street address

Doctor Sheikh Hospital

#### City

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shojam2@mums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of Nursing and Midwifery

#### Full name of responsible person

Doctor Fatemeh Heshmati Nabavi

#### Position

PHD of Nursing

#### Other areas of specialty/work

#### Street address

Ibn-e Sina St., Chaharah Doktora Crossing

#### City

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heshmatinf@mums.ac.ir

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

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Malihe Shoja

**Position**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*