

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

Mashhad

Postal code

91735-1358

Phone

+98 51 3723 6690

Fax

+98 51 3727 7470

Email

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

Mashhad

Postal code

9137913199

Phone

+98 51 3859 8016

Fax

+98 51 3859 7313

Email

heshmatinf@mums.ac.ir

Web page address

Person responsible for updating data

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

Mashhad

Postal code

91735-1358

Phone

+98 51 3726 9021

Fax

+98 51 3727 7470

Email

shojam2@mums.ac.ir

Web page address

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