

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of performing preoperative preparation program on schooled-aged childcare's anxiety

Protocol summary

Summary

This study will be conducted as randomized control trial in Amirkola Pediatric Hospital, Mazandaran, Iran. The purpose of this study is to evaluate the effects of preoperative preparation program on children's anxiety. The trial, will be performed on 122 children (7-12 years of age) admitted for elective surgery during 15 months. The researcher will randomly assign eligible participants into the experimental and control groups, after pre- test baseline anxiety measurement has taken while admission. The experimental group will receive supportive intervention and the control group will receive routine preoperative information and care. Before the operation the anxiety measurement will be repeated. The anxiety level is the main outcome and will be compared in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104106157N1**

Registration date: **2011-05-02, 1390/02/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-02, 1390/02/12

Registrant information

Name

Nazanin Vaezzadeh

Name of organization / entity

Mazandaran University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research chancellor of Mazandaran University of Medical Sciences

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2008-03-19, 1386/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of performing preoperative preparation program on schooled-aged childcare's anxiety

Public title

Assessment the effect of performing preoperative preparation program on childcare's anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children aged between 7-12 years, undergoing elective surgery, being able to speak and read Persian language, being accompanied by their mothers (as a close caregiver) on the preoperative assessment day and on the day of surgery. Exclusion criteria: Children who had previous surgery or hospitalization after the age of 18 months, developmental delay, use of anti-anxiety medications, chronic illness, and children whose parents were working in health care centers.

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research chancellor of Mazandaran University of
Medical Sciences

Street address

moalem street. moalem square

City

sari

Postal code

4816715793

Approval date

2007-03-12, 1385/12/21

Ethics committee reference number

85-147

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

CHILDREN'S ANXIETY

ICD-10 code

F41.9

ICD-10 code description

F41.9

Primary outcomes**1****Description**

Anxiety level

Timepoint

Before and after intervention

Method of measurement

Questionnaire, observation and record

Secondary outcomes

empty

Intervention groups**1****Description**

The supportive intervention in this study included a set of structured activities, designed to psychologically prepare children for surgery according to their developmental stage a day before the surgery. It is consist of a brief explanation on pre and postoperative care, which included information about pre operative fasting time, personal hygiene, control of vital signs, control of loosing teeth, location of dressing, wound care, use of analgesic drugs to relive pain after the surgery.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

amircola teaching therapiutic pediatric center

Full name of responsible person**Street address****City**

sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research chancellor of mazandadaran university of
medical sciences

Full name of responsible person

Dr. ahmadali enayati

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medical sciences, moalem square, moalem street

City

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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

Research chancellor of mazandadaran 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

Mazandaran University of Medical sciences

Full name of responsible person

nazanin vaezzadeh

Position

MSc./ Member of Faculty

Other areas of specialty/work

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City

Sari

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