

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of special designed care plan on clinical condition, child and parent anxiety of general surgery child from recovery unit discharge

Protocol summary

Summary

The present research is a parallel semi-experimental study conducted to investigate the influence of kids' special care program on the clinical state and anxiety of the child and parents who have undergone general surgery. This research will take place in 2016 during which 64 kids candidate for general surgery will be studied for 6 months from recovery up to the time when they were discharged. The entrance criteria included: aging 4 to 5 years old, having undergone a general surgery, gaining the agreement of both parents and the kid, and having one of the parents as the attendant with kid. The exit criteria included: especial problems during operation or anesthesia, a background of hospitalization and surgery, and a background of chronic diseases. The patients will be randomly divided into the control and test groups. The control group received the routine post-surgery cares in recovery room from nurses. As of the intervention group, personnel will attend classes and receive practical or question and answer training's in accordance with educational demands and care standards of their ward. In this group, parents are allowed to visit the kid while he is in recovery room. The clinical state and the anxiety of the kid and parents before and after surgery will be checked in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030526918N1**

Registration date: **2016-06-15, 1395/03/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-15, 1395/03/26

Registrant information

Name

Saeid Pasban Noghabi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 915 655 4507

Email address

s.pasban@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research; Tarbiat Modares university.

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2016-09-10, 1395/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of special designed care plan on clinical condition, child and parent anxiety of general surgery child from recovery unit discharge

Public title

The effect of special designed care plan on clinical condition, child and parent anxiety of general surgery child from recovery unit discharge

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 4-5 years old; have general surgery; Satisfaction of parents; Attend of

parent. Exclusion criteria: History of hospitalization; History of chronic disease.

Age

From **4 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Not 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

Ethics committee of Tarbiat Modares University .

Street address

Tehran, Iran

City

Tehran

Postal code

Approval date

2015-04-28, 1394/02/08

Ethics committee reference number

IR.TMU.REC.1394.41

Health conditions studied

1

Description of health condition studied

Anxiety of child and parents

ICD-10 code

F93.0

ICD-10 code description

Separation anxiety disorder of childhood

2

Description of health condition studied

Clinical condition of child

ICD-10 code

Z09.0

ICD-10 code description

Follow-up examination after surgery for other conditions

Primary outcomes

1

Description

Child Anxiety

Timepoint

Before and after surgery

Method of measurement

Designed tool

2

Description

Parent Anxiety

Timepoint

Before and after surgery

Method of measurement

Spilberger questionnaire

3

Description

Clinical condition of child

Timepoint

Before surgery; recovery and in surgery ward

Method of measurement

Designed tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Inter-section education for nurse in 7-10 Session. We use pamfelet, Practical training, poster and computer.

Category

Prevention

2

Description

Control group: No intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Sheikh Hospital

Full name of responsible person

Saeid Pasban-Noghabi

Street address

Majd street, Doctor Sheikh Hospital.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Tarbiat Modares School of Medical Sciences.

Full name of responsible person

Yaghob Fathollahi

Street address

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research, Tarbiat Modares School 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

Department of Nursing; School of Medical Sciences; Tarbiat Modares University.

Full name of responsible person

Saeid Pasban-Noghabi

Position

Student

Other areas of specialty/work

Street address

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Nursing; School of Medical Sciences; Tarbiat Modares University.

Full name of responsible person

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Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

Other areas of specialty/work

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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