

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Impact of parental presence during induction of anesthesia on anxiety level among pediatric patients and their parents

Protocol summary

Summary

Anesthesia induction is a stressful event for children and their parents, and may have potentially harmful consequences to the patient's physiological and mental situation. Traumatic anesthesia induction has psychological consequences that recur with repeated anesthesia, increase pediatric discomfort during the recovery period, and may even induce reactionary postoperative behavior. The aim of this study is to assess the impact of parental presence during induction of anesthesia on anxiety scores in pediatric patients. This clinical trial will be performed on two groups of 48 children with ASA 1 and 2 undergoing elective minor surgery at Mofid Children Hospital. Parents unwilling to continue the study will be excluded. Both groups will receive Midazolam 0.5 mg/kg at least 20 minutes before surgery but in case group one of the parents will be present in the operating room until induction of anesthesia and loss of consciousness of the patient. Anxiety in children (m-YPAS), parental anxiety (STAI), cooperation of patient with anesthesiologist at induction of anesthesia (ICC) and parental satisfaction (VAS) will be measured. Data collected in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011931497N4**
Registration date: **2017-02-16, 1395/11/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-16, 1395/11/28

Registrant information

Name

Afsaneh Sadeghi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of parental presence during induction of anesthesia on anxiety level among pediatric patients and their parents

Public title

Impact of parental presence on preoperative anxiety of children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients age 4-10 years with ASA 1 or 2 without history of psychiatric disorders and drugs undergoing elective minor surgery such as inguinal or

umbilical hernias ;surgeries less than 1-hour duration
with no significant changes in the patient's
hemodynamic parameters Exclusion criteria:Parents
unwilling to continue the study

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

N/A

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

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Science

Street address

Arabi Ave,Daneshjoo Blvd,Velenjak Ave

City

Tehran

Postal code

Approval date

2010-07-04, 1389/04/13

Ethics committee reference number

87/225

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Preoperative anxiety in children

Timepoint

At ward,at preparation room and immediately before
induction of anesthesia

Method of measurement

Modified Yale Preoperative Anxiety Scale

2

Description

Parental anxiety

Timepoint

At ward,at preparation room,immediately before
induction of anesthesia

Method of measurement

State And Trait Anxiety Scale

Secondary outcomes

1

Description

Cooperation of child with anesthesiologist at induction of
anesthesia

Timepoint

At induction of anesthesia

Method of measurement

Induction Compliance Checklist

2

Description

parental satisfaction

Timepoint

After induction of anesthesia

Method of measurement

visual analog scale

Intervention groups

1

Description

In control group there is no intervention

Category

N/A

2

Description

In intervention group,parents are present at induction of
anesthesia until loss of consciousness.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children Hospital

Full name of responsible person

Afsaneh Sadeghi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afsaneh Sadeghi

Street address

Arabi Ave,Daneshjoo Blvd,Velenjak Ave

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afsaneh Sadeghi

Position

Anesthesiologist

Other areas of specialty/work

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Afsaneh Sadeghi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

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