

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of Painting on Children's Anxiety before Surgery in the Operating Room

#### Protocol summary

##### Study aim

Determination of the effect of painting on children's anxiety before surgery in the operating room of Alzahra Hospital in Isfahan in 2017

##### Design

a controlled trial, parallel Two arm parallel group none-randomized controlled trial and open-labile

##### Settings and conduct

In this study, the children who referred to the operating room in Alzahra hospital, Isfahan, Iran were assigned to control and experimental groups based on weekly visits. After the presentation of the research aims for the parents the researcher completed the anxiety questionnaire. After completing the informed consent form by the parents in the intervention group, 15 minutes were taken to draw the painting. There was no intervention in the control group. In order to increase the accuracy, the researcher completed the questionnaire before and after the intervention by observing the child's behavior

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 3 to 7 years ; undergoing surgery in Alzahra Hospital in Isfahan ; Consent Inform from parents and children Exclusion criteria: The child with a Cognitive disability is confirmed by the parents; The child with a mental illness is confirmed by the parents

##### Intervention groups

In this study, 70 children aged 3 to 7 years undergoing surgery were randomly allocated into intervention and control groups (n = 35). The children in the intervention group painted in the preoperative room and their anxiety was measured before and after painting. There was no intervention in the control group except for routine interventions. The data collection tool consisted an Anxiety questionnaire

##### Main outcome variables

children's anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171118037521N1**

Registration date: **2018-04-02, 1397/01/13**

Registration timing: **retrospective**

Last update: **2018-04-02, 1397/01/13**

Update count: **0**

##### Registration date

2018-04-02, 1397/01/13

##### Registrant information

##### Name

narges Sadeghi

##### Name of organization / entity

Isfahan (Khorasgan) Branch, Islamic Azad University, Isfahan, Iran.

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3535 4058

##### Email address

narges\_sadeghi@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-05-21, 1396/02/31

##### Expected recruitment end date

2017-07-22, 1396/04/31

##### Actual recruitment start date

2017-05-21, 1396/02/31

##### Actual recruitment end date

2017-08-15, 1396/05/24

##### Trial completion date

empty

## Scientific title

The effect of Painting on Children's Anxiety before Surgery in the Operating Room

## Public title

The effect of painting on children's anxiety

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The age range was 3 to 7 years. The ability to communicate verbally The ability to draw paintings Conscious Consent of Parents and Children

### Exclusion criteria:

The child with a Cognitive disability is confirmed by the parents The child with a mental illness is confirmed by the parents

## Age

From **3 years** old to **7 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

Actual sample size reached: **70**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

This study has not been randomized.

## 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

Ethics committee of Islamic Azad University

##### Street address

Isfahan (Khorasgan) Branch, Arghavanieh, Jey St;  
Isfahan, Iran.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81551-39998

## Approval date

2017-05-22, 1396/03/01

## Ethics committee reference number

IR.IAU.KHUISF.REC-1396-2-3

## Health conditions studied

### 1

#### Description of health condition studied

##### ICD-10 code

F43

##### ICD-10 code description

Reaction to severe stress, and adjustment disorders

## Primary outcomes

### 1

#### Description

Percentage of people with decreasing anxiety

#### Timepoint

When entering the room before surgery, and about 20-15 minutes after attending the desired room

#### Method of measurement

Yale Preoperative Anxiety Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, after obtaining informed consent from the family and the child, in the per-operative room, drawing equipment such as color pencil and simple painting notebook were placed in a suitable place. The children painted in the preoperative room. The minimum waiting time for entering the operating room was 15 minutes. The children of the intervention group painted at least 15 minutes. The children's anxiety questionnaire completed before and after children painting by the researcher.

#### Category

Prevention

### 2

#### Description

Control group: In this group, after obtaining informed consent from the family and the child, before the surgery and 15 minutes later, the children's anxiety questionnaire was completed by the researcher. There was no intervention in this group.

#### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Al-Zahra Hospital in Isfahan

**Full name of responsible person**

Narges Sadeghi

**Street address**

Islamic Azad University Isfahan Branch (Khorasgan)  
Arghavanieh, Jey St; Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81551-39998

**Phone**

+98 31 3535 4059

**Email**

narges\_sadeghi@nm.mui.ac.ir

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Sadeghi

**Street address**

Islamic Azad University, Isfahan (Khorasgan) Branch,  
Arghavanieh, Jey St; Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81551-39998

**Phone**

+98 31 3535 4059

**Fax**

+98 31 3535 4065

**Email**

n45sadeghi@yahoo.com

**Web page address****Grant name**

Isfahan Islamic Azad University

**Grant code / Reference number**

000000

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

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Sadeghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Islamic Azad University, Isfahan (Khorasgan) Branch,  
Arghavanieh, Jey St; Isfahan, Iran.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81551-39998

**Phone**

+98 31 3535 4059

**Email**

narges\_sadeghi@nm.mui.ac.ir

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Sadeghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Islamic Azad University, Isfahan (Khorasgan) Branch,  
Arghavanieh, Jey St; Isfahan, Iran.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81551-39998

**Phone**

+98 31 3535 4059

**Email**

narges\_sadeghi@nm.mui.ac.ir

### Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Narges Sadeghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Islamic Azad University, Isfahan (Khorasgan) Branch,  
Arghavanieh, Jey St; Isfahan, Iran.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81551-39998

**Phone**

+98 31 3535 4059

**Fax****Email**

n45sadeghi@yahoo.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there isn't more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available