

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### A comparative Study of the effect of painting therapy and drug therapy on the anxiety of children undergoing tonsillectomy

#### Protocol summary

##### Study aim

Determination and comparison of the effect of painting therapy and Midazolam on the level of anxiety in children undergoing tonsillectomy

##### Design

Clinical trial on 90 children with control group, non blinded; randomized based on random numbers table.

##### Settings and conduct

the anxiety level of children undergoing tonsillectomy aged 5 to 12 years in the operating room of Imam Khomeini Hospital in Kermanshah during the years of 97-98 will be measured .Children will be divided into three groups of painting,drug and control group.Then the anxiety level will be measured for each group at the entrance to the waiting room. After intervention ,in the operating room on the bed and before anesthesia, their anxiety level will be measured again using the VAS-A, STAIC, and mYPAS anxiety scales.

##### Participants/Inclusion and exclusion criteria

Participants are children who undergo tonsillectomy surgery. Inclusion criteria are: Admission of patient at the night before surgery Children between 5 and 12 years Informed consent of parents Exclusion criteria: Physiological and psychological diseases Previous surgery history Previous anesthesia history Consumption of special drugs Dissatisfaction of parents

##### Intervention groups

The samples consist of three groups of painting therapy, drug therapy and control. The control group will include children who have not taken an intervention and they will receive routine cares. The painting group is placed under the intervention of a painting with markers and color pencil before surgery, and they will color caricature images of the operating room. The drug group will receive 0.020 mg / kg IV midazolam before surgery.

##### Main outcome variables

Anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181117041683N1**

Registration date: **2019-02-05, 1397/11/16**

Registration timing: **prospective**

Last update: **2019-10-15, 1398/07/23**

Update count: **1**

##### Registration date

2019-02-05, 1397/11/16

##### Registrant information

##### Name

Samane Babaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3424 3873

##### Email address

s.babaei7203@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### Actual recruitment start date

2019-03-09, 1397/12/18

##### Actual recruitment end date

2019-07-11, 1398/04/20

##### Trial completion date

2019-07-11, 1398/04/20

##### Scientific title

A comparative Study of the effect of painting therapy and drug therapy on the anxiety of children undergoing tonsillectomy

#### Public title

Effect of painting therapy and midazolam on anxiety

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Admission of patient at the night before surgery Children between 5 and 12 years Type of surgery: Tonsillectomy Consent of parents

##### Exclusion criteria:

Physiological and psychological disease Surgery history Anesthesia history Consumption of special drugs Dissatisfaction of parents

#### Age

From **5 years** old to **12 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

Actual sample size reached: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Initial sampling will be available in a non-randomized way. Then, the samples in this study will be assigned by random allocation of patients in the study groups (control, medication intervention and artistic intervention). Samples will be assigned to three groups by random sampling block Permutation. In this way, the study will continue until the number of samples has been completed. To implement this randomization method, the following will be done: 1. The total sample size and sample size ratio will be specified in the groups. 2. Single digit numbers between 0 and 9 will be selected from random numbers table. 3. For studies with 3 groups, numbers 0-9 will be divided into 3 equal blocks, with the probability of allocating one to each block will be 0.5. Block 1-3 will be used for the first group and block 4-6 for the second group and block 7-9 for the third group. It will be determined by numbers selected from random numbers table and blocks determination that anyone who has entered the study will be placed in which group.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Similar studies have been conducted on several surgeries, but none have studied just one particular surgery. Since the type of surgery affects the amount of anxiety, we have studied only the tonsillectomy surgery,

which is the second most commonly used surgical procedure in children. Recent studies have also compared some supportive interventions with midazolam, but none of these studies have compared painting therapy alone with midazolam.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

##### Street address

Dolatabad, School of Kermanshah Paramedicine

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6719851351

#### Approval date

2018-12-05, 1397/09/14

#### Ethics committee reference number

IR.KUMS.REC.1397.684

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

Tonsillectomy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Preoperative anxiety score in anxiety scale

#### Timepoint

1. Before intervention in the waiting room. 2. After intervention and in the operating room at induction of anesthesia

#### Method of measurement

1-State and Trait Anxiety Inventory scale 2-Visual Analogous Scale 3-modified Yale Preoperative Anxiety Scale

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Drug therapy - Midazolam hydrochloride - 0/020mg / kg - Single intravenous injection - Pharmaceutical chemistry

### Category

Treatment - Drugs

2

### Description

Intervention group: Painting Therapy with Stedler color pencil and marker made in Germany. Asking children to paint about what they imagine about operating room and also providing colorless pictures and caricatures (about operating room and surgical team) to be colored by children.

### Category

Treatment - Devices

3

### Description

Control group: Routin care

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam khomeyni hospital

#### Full name of responsible person

Samane Babaei

#### Street address

Naghliye Ave, Imam khomeyni hospital

#### City

Kermanshah

#### Province

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#### Postal code

6718743161

#### Phone

+98 83 3728 5054

#### Fax

+98 83 3722 4516

#### Email

ihosp@kums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Farid Najafi

#### Street address

Shahid Beheshti Blvd., Building No. 2, Kermanshah University of Medical Sciences

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6715847141

#### Phone

+98 83 3838 4185

#### Email

farid\_n32@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Kermanshah University of Medical Sciences

### 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

Kermanshah University of Medical Sciences

#### Full name of responsible person

Samane Babaei

#### Position

MSc student of surgical technology

#### Latest degree

Bachelor

#### Other areas of specialty/work

Others

#### Street address

Isar Square, Dolatabad Blvd, Paramedical School, Operative Group

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**Email**

S.babaei7203@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

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**Position**

MSc student of surgical technology

**Latest degree**

Bachelor

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Others

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Kermanshah University of Medical Sciences

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S.babaei7203@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available