Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 recieve routin 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, wich 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
Tonsilectomy
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 Analoguous 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
Kermanshah
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
City
Kermanshah
Province
Kermanshah
Postal code
6719851351
Phone
+98 83 3826 2042

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
Samane Babaei
Position
MSc student of surgical technology
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Phone
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Email
S.babaei7203@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Samane Babaei
Position
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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