Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

A comparative study of the effect of play dough and inflating balloons on pediatric anxiety before surgery.

Protocol summary

Study aim
Comparison of the effect of play dough and balloon inflation on children's anxiety before surgery

Design
Clinical trial with control group, with parallel groups, block randomization on 60 patients with blocks of size 6 (based on the method of generating random numbers in the computer) will be divided into two intervention groups and one control group.

Settings and conduct
This study will be conducted on 4-8 year old children who are candidates for elective surgeries in Besat Hospital Hamedan without their parents present in the waiting room of the operating room.

Participants/Inclusion and exclusion criteria
4-8 years old children, selective surgeries, ability to communicate verbally, ability to use the mouth, ability to use fingers, cognitive ability and absence of mental and mental illness according to parents' approval, parental consent, children undergoing surgery with general anesthesia, absence of parents As an interventional agent before surgery and children who are physically placed in status I and II according to the standards of the American Society of Anesthesiology.

Intervention groups
Play dough recipient group: including playing with dough produced by Aria company and also using play doughs that have peripheral equipment, is implemented in the second intervention group (balloons) and breathing exercises including blowing up balloons by placing balloons. A simple color inside a glass container and the choice of the child's favorite balloon is done by himself,Control group: routine hospital interventions will be performed in this group.

Main outcome variables
Comparison of the effect of play dough and balloon inflation on children's anxiety before surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230514058183N1**
Registration date: **2023-11-19, 1402/08/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-19, 1402/08/28**
Update count: **0**

Registration date
2023-11-19, 1402/08/28

Registrant information

Name
Razie vakili

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-03, 1402/05/12

Expected recruitment end date
2024-01-31, 1402/11/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

A comparative study of the effect of play dough and inflating balloons on pediatric anxiety before surgery.

Public title
the effect of play dough and inflating balloons on pediatric anxiety.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 4-8 Elective surgeries Children with the ability to communicate verbally Children with the ability to use the mouth Children with the ability to use fingers Children with cognitive ability and absence of mental illness, approved by parents Parental consent Children undergoing surgery with general anesthesia Absence of parents as an intervening factor before surgery Children who are physically placed in status I and II according to the standards of the American Society of Anesthesiology
Exclusion criteria:
Lack of consent to participate in the study
Age
From **4 years** old to **8 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A random sequence will be generated using random blocks with blocks of 6 for a total of 10 blocks that will be generated using the website https://www.sealedenvelope.com. The person who collects the data is unaware of the type of description of the samples into the study groups. Concealment of random allocation will be done using opaque sealed envelopes with a random sequence. The people participating in the study are randomly divided into two model groups and one control group using the block randomization method with blocks of size 6 (based on the method of generating random numbers in the computer). After completing the demographic information checklist by the parents, the child is placed in one of the three groups based on random numbers that are determined in advance.
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 Kermanshah University of Medical Sciences
Street address
Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard ,Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2023-08-01, 1402/05/10
Ethics committee reference number
IR.KUMS.REC.1402.177

Health conditions studied

1

Description of health condition studied
The effect of inflating balloons and play dough on children's imagination
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety
Timepoint
The initial anxiety score is evaluated 5 minutes before the intervention in the waiting room by anxiety measurement tools and scales, and after the surgery, which will last about an hour.
Method of measurement
STAIC, VAS-A and m-YPAS are used to measure anxiety

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: inflating balloons.includes blowing up balloons by placing simple colored balloons in a container and choosing the child's favorite balloon by himself. In this way, after choosing his favorite balloon, he starts to inflate the balloon.Community Verified icon
Category
Treatment - Devices

2

Description
Intervention group: group receiving play dough: play therapy includes playing with dough produced by Aria company and also using play doughs that have peripheral equipment. The aim of this intervention is for children to visualize the desired object in their mind and then use the sense of touch to make the desired object for 15 minutes 15 minutes before the surgery (first time).

Category
Treatment - Devices

3

Description
Control group: Routine hospital interventions will take place in this group(Among the benzodiazepines, midazolam, diazepam, and lorazepam are often administered orally or intravenously for pre-Medications are prescribed).

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
بیمارستان بعثت

Full name of responsible person
پریسا ریزه وندی

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
Razie Vakili

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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