Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of oral ketamine and promethazine effect as anesthetic premedication on preoperative anxiety of children ages 3 to 8 years

Protocol summary

Study aim
Comparison of oral ketamine and promethazine effect as anesthetic premedication on preoperative anxiety of children ages 3 to 8 years

Design
The present study is a quasi-experimental clinical trial study with parallel groups and a control group in which the available sampling method is used. Sample size is determined based on Cochran's formula of at least 60 pieces that are randomly classified into 3 groups A, B and C

Settings and conduct
Tonekabon Shahid Rajaei Hospital. Patients receive the drug before entering the operating room without knowing the type of oral medication and their anxiety level is assessed by the researcher according to the Visual Facial Scale criteria before receiving the premedication and also 30 minutes after it.

Participants/Inclusion and exclusion criteria
Admission: Children 3 to 3 years old candidate for surgery in hospital No entry: Children with underlying anxiety disorder and children whose parents (one or both) have underlying anxiety disorder

Intervention groups
Group A includes children 3 to 8 years of age who will receive 5 mg / kg oral ketamine diluted with 20% dextrose to a volume of 0.2cc / kg 30 minutes before entering the operating room. Group B includes children 3 to 8 years old. For 30 years before entering the operating room, they will receive 1 mg / kg oral promethazine (promethazine syrup 5 mg / 5 ml) and group C or control will consist of children who 30 minutes before entering the operating room only "0, 2cc / kg will receive 20% dextrose without any anesthetic.

Main outcome variables
Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200921048789N1**
Registration date: **2020-09-23, 1399/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-23, 1399/07/02**
Update count: **0**

Registration date
2020-09-23, 1399/07/02

Registrant information
Name
Sepehr Edalat khah
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4424 2961
Email address
sepehr.edalatkhah@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of oral ketamine and promethazine effect as anesthetic premedication on preoperative anxiety of children ages 3 to 8 years

Public title
Comparison of oral ketamine and promethazine effect as anesthetic premedication on preoperative anxiety of children ages 3 to 8 years
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All children 3 to 3 years old are candidates for surgery in the hospital
Exclusion criteria:
Children with underlying anxiety disorder Children whose parents (one or both) have underlying anxiety disorders
Age
From **3 years** old to **8 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The study is a quasi-experimental clinical trial study in which the available sampling method is used. Sample size is determined based on Cochran's formula of at least 60 pieces that are randomly classified into 3 groups A, B and C
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, participants and their parents as well as data analyzers are not aware of the type of drug received and the researcher randomly reviews drugs in 3 groups A B C on patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Tonekabon Branch
Street address
Islamic Azad Univercity Tonekabon Branch, Valiabad, Tonekabon
City
Tonekabon
Province
Mazandaran
Postal code
4684161167
Approval date
2019-06-02, 1398/03/12
Ethics committee reference number
IR.IAU.TON.REC.1398.004

Health conditions studied

1

Description of health condition studied
Premedication
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety
Timepoint
In two times: before receiving the oral premedication and 30 minutes after receiving it
Method of measurement
According to the visual facial scale criterion in 6 states: without anxiety, mild anxiety, mild to moderate, moderate, moderate to severe and severe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group A includes children 3 to 8 years of age who will receive 5 mg / kg oral ketamine diluted with 20% dextrose to a volume of 0.2cc / kg 30 minutes before entering the operating room.
Category
Treatment - Drugs

2

Description
Intervention group: Group B includes children 3 to 8 years old who will receive 1mg / kg oral promethazine 30 minutes before entering the operating room. (Promethazine syrup 5mg / 5ml)
Category

Treatment - Drugs

3

Description
Control group: Group C or control will consist of children who will receive only 0.2cc / kg of 20% dextrose without any anesthesia 30 minutes before entering the operating room.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tonekabon shahid rajaei hospital
Full name of responsible person
Sepehr Edalat khah
Street address
Emam Khomeini St.
City
Tonekabon
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 5423 7001
Email
sepehr.edalatkhah@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nemat Rostami
Street address
Islamic Azad Univercity Tonekabon Branch, Valiabad, Tonekabon
City
Tonekabon
Province
Mazandaran
Postal code
4684161167
Phone
+98 11 5427 1151
Email
nrostami60@iauc.ac.ir
Grant name
Grant code / Reference number
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
Sepehr Edalat khah
Position
Medical Intern
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No 1, Third Alley, Third Armakan St., Ale Ahmad Ave.
City
Tehran
Province
Tehran
Postal code
1463645764
Phone
+98 21 4424 2961
Email
sepehr.edalatkhah@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Sepehr Edalat khah
Position
Medical intern
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Other areas of specialty/work
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Postal code
1463645764
Phone

+98 21 4424 2961

Fax

Email

sepehr.edalatkhah@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sepehr Edalat khah

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

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Fax

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after being unidentified

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

All researchers and colleagues in this field

Under which criteria data/document could be used

For therapeutic and research purposes and by mentioning the names of the authors of the article

From where data/document is obtainable

Sepehr Edalat khah

What processes are involved for a request to access data/document

Send an email to Sepehr Adalatkhah and receive data and documents if needed in the shortest time

Comments