

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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 University 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 University 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

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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