

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effect of Promethazine on reduction of restlessness during eye trauma examinations in children referred to Zazdeh Zahedan Ophthalmology Hospital, 2017-2018

Protocol summary

Study aim

Determining of the effect of Promethazine on reduction of restlessness during eye trauma examinations in children referred to Zazdeh Zahedan Ophthalmology Hospital, 2017-2018

Design

Clinical trial with control group, on the one hand blind, random

Settings and conduct

In this study, children with visual impairment who met the criteria for our study will be assessed for their anxiety by receiving promethazine. Two groups of 31 children matched in this study were evaluated. Promethazine receptor group and placebo receptor group. Finally, children's behavior is assessed and their anxiety is monitored through the Cohen-Mansfield questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1 - Children 2 to 7 years 2 - Having satisfaction and willingness to cooperate with parents 3. No history of seizures and current use of anticonvulsants 4- Lack of liver disease (hepatitis) 5. Lack of coagulation problems 6- Optimism Output Criteria: Lack of willingness to continue cooperation during the study

Intervention groups

Promethazine Receiver Group: 0.5 mg/Kg Control group: placebo recipient (water as much as promethazine receiver group)

Main outcome variables

Aggressive behavior during the examination; Shocking movements during the examination; Anxiety during the examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200406046969N1**

Registration date: **2020-06-14, 1399/03/25**

Registration timing: **retrospective**

Last update: **2020-06-14, 1399/03/25**

Update count: **0**

Registration date

2020-06-14, 1399/03/25

Registrant information

Name

Somayeh Moradi Afrapli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3337 2151

Email address

s.m.a09301094443sma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Promethazine on reduction of restlessness during eye trauma examinations in

children referred to Zazdeh Zahedan Ophthalmology Hospital,2017-2018

Public title

The effect of promethazine on reducing children's restlessness during eye examinations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 2 to 7 years Satisfaction and willingness to cooperate with parents Lack of history of seizures and current use of anticonvulsant drugs Lack of liver disease (hepatitis) Lack of coagulation problems

Exclusion criteria:

Parental unwillingness to study

Age

From **2 years** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups. The two groups will be matched in terms of age and sex by randomized classification of blockchain blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the blinding method of a sucrose was used. In this way, children and their parents will not be aware of the type of medication used (promethazine or multivitamin). This is done to prevent distortion of the study results. To blind the type of drug used, both drugs will be poured into opaque glass of the same color and without labels. And families don't know what kind of medicine to take.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Dr. Hesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2020-03-01, 1398/12/11

Ethics committee reference number

IR.ZAUMS.REC.1398.430

Health conditions studied

1

Description of health condition studied

Restlessness of children during the examination

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of restlessness during eye examinations

Timepoint

20 minutes after taking the drug

Method of measurement

Based on behavioral observation-researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take 1 dose of promethazine syrup 20 minutes before the eye exam in the amount of 0.5 mg /kg

Category

Treatment - Drugs

2

Description

Control group: Water bottle in glass similar to Promethazine syrup

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Al-Zahra Ophthalmology Hospital

Full name of responsible person

Mohammad Hossein Validad

Street address

Zahedan city - Dr. Hesabi Square - Zahedan
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Fax**Email**

mhovalidad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

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Zahedan city - Dr. Hesabi Square - Zahedan
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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad Hossein Validad

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be fully collected and published in spss software files.

When the data will become available and for how long

After the final approval of the dissertation by the supervisors

To whom data/document is available

Officials of the Research Ethics Committee and statistical and supervisory professors

Under which criteria data/document could be used

After analyzing the data, if approved by the supervisor and statistical consultant, the data can be viewed.

From where data/document is obtainable

First supervisor and statistical professor of study and ethics committee of Zahedan University of Medical Sciences

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

First, the application is submitted to the ethics committee, then the application is given to the study guide professor, and finally the statistical consultant professor, and if all three items are approved, the data is published.

Comments