Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 54 3337 2151

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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 University of Medical Sciences campus

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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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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 HosseinValidad

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