Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of the preventive effects of Aminophylline, Plasil and Paracetamol on the pain intensity after strabismus surgery

Protocol summary

Study aim
Evaluation of the preventive effects of aminophylline, plasil and paracetamol on the pain intensity after strabismus surgery

Design
Clinical trial with control group and three parallel groups double blinded randomized

Settings and conduct
This is a double-blinded clinical trial, performed on 120 patients underwent strabismus correction surgery in Feiz hospital, Isfahan. Patients were randomized into 4 groups: Aminophylline, plasil, paracetamoland placebo. After surgeries, patients were assessed with Visual Analogue Scale (VAS) to evaluate their pain. Also Hemodynamic parameters, extubation and recovery time after surgeries were also evaluated.

Participants/Inclusion and exclusion criteria
inclusion criteria were: absence of any history of allergic reactions to Aminophyllinem paracetamol or plasil, absence of history of chronic pain more than 6 months, abbsence of taking analgesics, paracetamol, aminophylline or plasil in 24 hours before the study and filled written informed consent.

Intervention groups
Group 1 taking Paracetamol. Group 2 taking Plasil. Group 3 taking Aminophylline. Control group taking no medication

Main outcome variables
Pain intensity after strabismus surgery meaningfully different; arterial blood pressure meaningfully different; heart rate meaningfully different.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150106020588N6**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **retrospective**

Last update: **2019-07-28, 1398/05/06**
Update count: **0**

Registration date
2019-07-28, 1398/05/06

Registrant information

Name
Darioush Moradi Farsani

Name of organization / entity
Isfahan Univesity of Medical Sciences

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Iran (Islamic Republic of)

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+98 31 3625 5555

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-07, 1396/02/17

Expected recruitment end date
2017-09-23, 1396/07/01

Actual recruitment start date
2017-08-03, 1396/05/12

Actual recruitment end date
2017-09-23, 1396/07/01

Trial completion date
2018-01-15, 1396/10/25

Scientific title
Evaluation of the preventive effects of Aminophylline, Plasil and Paracetamol on the pain intensity after strabismus surgery

Public title
Evaluation of the preventive effects of Aminophylline

Plasil and Paracetamol on the pain intensity after strabismus surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
abbsence of taking analgesics, paracetamol, aminophylline or plasil in 24 hours before the surgery
Filled written informed consent

Exclusion criteria:
Any background of allergy to Aminophylline Plasil and Paracetamol Reporting chronic pain prolonged more than 6 months

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
parients were randomized by using computer softwares and randomly entered to the study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The main researcher was blind and wasn't aware of which patient belongs to which group. The data collectors ware blind and weren't aware of which patient belongs to which group. The participants were bling and weren't aware of their own groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
hezar jarib

City
Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱۸۱۷۴۶

Approval date
2017-05-25, 1396/03/04

Ethics committee reference number
IR.MUI.1396.3.440

Health conditions studied

1

Description of health condition studied
strabismus

ICD-10 code
H50.1

ICD-10 code description
Exotropia

Primary outcomes

1

Description
Intensity of pain after strabismus surgery

Timepoint
entering the recovery, 30 , 60 mins and 2 , 4,8,16,24 hours after entering to recovery

Method of measurement
VAS

Secondary outcomes

empty

Intervention groups

1

Description
Control group: no intervention

Category
N/A

2

Description
Intervention group: 0.1 mg per kg Metoclopiramide slow IV 15 mins befor surgery ends.

Category
Treatment - Drugs

3

Description
Intervention group: 3mg per kg Aminophylline 15 mins before surgery ends

Category
Treatment - Drugs

4

Description
Intervention group: 1g Paracetamol IV infusion 15 mins before surgery ends
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Hospital
Full name of responsible person
Dr Daryoush Moradi
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Feiz hospital, modarres street, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mehdi Nematbakhsh
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Research deputy, Isfahan University of Medical Sciences, Hezarjarib street, Isfahan
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Web page address
https://research.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Darioush Moradi Farsani
Position
Associate professor
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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
All data
When the data will become available and for how long
6 months after publishing
To whom data/document is available
Researchers
Under which criteria data/document could be used
Statistics analysis
From where data/document is obtainable
Email of scientific author
What processes are involved for a request to access data/document
Checking email of who wants data
Comments