

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

Registration timing: **retrospective**

Study aim

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

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

Update count: **0**

Registration date

2019-07-28, 1398/05/06

Design

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

Registrant information

Name

Darioush Moradi Farsani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3625 5555

Email address

dmoradi@med.mui.ac.ir

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, paracetamol and 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.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

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

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

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.

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150106020588N6**

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

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:

absence 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

patients 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 were blind and weren't aware of which patient belongs to which group. The participants were blind 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

Isfahan

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 Metoclopramide slow IV 15 mins before 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

Street address

Feiz hospital, modarres street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8196711111

Phone

+98 31 3445 2034

Email

behrouzesf91@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Research deputy, Isfahan University of Medical Sciences, Hezarjarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8196711111

Phone

+98 31 3792 8091

Email

behrouzesf91@gmail.com

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

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Isfahan University of Medical Sciences, Hezarjrib street

City

Isfahan

Province

Isfahan

Postal code

8196711111

Phone

+98 31 3625 5555

Fax

Email

dmoradi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Darioush Moradi Farsani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Isfahan University of Medical Sciences, Hezarjrib street

City

Isfahan

Province

Isfahan

Postal code

8196711111

Phone

+98 31 3625 5555

Fax**Email**

dmoradi@med.mui.ac.ir

dmoradi@med.mui.ac.ir

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Darioush Moradi Farsani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Isfahan University of Medical Sciences, Hezarjrib street

City

Isfahan

Province

Isfahan

Postal code

8196711111

Phone

+98 31 3625 5555

Fax**Email**