

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Preemptive effect of aminophylline, ketamine and paracetamol on pain intensity after deep vitrectomy surgery

Protocol summary

Study aim

Evaluating and comparing effect of aminophylline, ketamine and paracetamol on reduction of postoperative pain after deep vitrectomy surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 240 patients. Randomization allocation software is used for randomization and patients are also divided into 4 parallel groups including ketamine, acetaminophen, aminophylline and placebo.

Settings and conduct

In this clinical study, patients are divided into 4 parallel groups including ketamine, acetaminophen, aminophylline and placebo, and the pain intensity in the study groups are evaluated up to 24 hours after surgery. The anesthesiologist, data collector and statistical analyzer are blinded about the type of groups. It is noteworthy that the drugs are prepared in the same containers and the same shape.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients undergoing deep vitrectomy, aged between 40 to 80 years and American society of anesthesiologists physical status I or II. Exclusion criteria: cardiac arrest during surgery and any complications that are required an alteration in anesthesia methods.

Intervention groups

Intervention group 1: About 0.15mg/kg of ketamine with 100 cc of normal saline are injected intravenous 20 minutes before surgery ending. Intervention group 2: About 1g of acetaminophen with 100 cc of normal saline are injected intravenous 20 minutes before surgery ending. Intervention group 3: About 3 mg/kg of aminophylline with 100 cc of normal saline are injected intravenous 20 minutes before surgery ending. Intervention group 4: 100 cc of normal saline is injected intravenous 20 minutes before surgery ending.

Main outcome variables

Postoperative pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210919052523N1**

Registration date: **2021-10-07, 1400/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-07, 1400/07/15**

Update count: **0**

Registration date

2021-10-07, 1400/07/15

Registrant information

Name

Keyvan Ghadimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 8060

Email address

keyvanghadimi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Preemptive effect of aminophylline, ketamine and paracetamol on pain intensity after deep vitrectomy surgery

Public title
The effect of aminophylline, ketamine and paracetamol on pain severity after emptying of vitreous

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Ages 40 to 80 years American society of anesthesiologists (ASA) physical status I or II Undergoing deep vitrectomy
Exclusion criteria:
Cardiac arrest during surgery Any complications that required an alteration in anesthesia methods

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description
Each of the patients is provided with a particular number by Random Allocation software allocated them to an intervention group. Each patient is provided with a particular number. Cases with numbers corresponded for 4*k are allocated to ketamine group, those with numbers corresponded for 4*k+1 are allocated to acetaminophen, those with numbers corresponded for 4*k+2 are allocated to the aminophylline group and those with numbers corresponded for 4*k+3 are allocated to placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients are divided into groups 1 to 4 and no one knows the type of groups except the manager. Patients are received the same number of drugs based on group number, as well as anesthesiologist, data collector and statistical analyzer are blinded of grouping types. It is noteworthy that the drugs are prepared in the same containers and the same shape that the blinding is done completely.

Placebo
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 Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

IR.MUI.REC.1396.3.876

Health conditions studied

1

Description of health condition studied

Disorders of vitreous

ICD-10 code

H43

ICD-10 code description

Disorders of vitreous body

Primary outcomes

1

Description

Postoperative pain

Timepoint

Arrival to recovery and then at 15 and 30 minutes, 2, 4, 8, and 24 after entry to recovery unit

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 minutes before surgery ending,

about 0.15mg/kg of ketamine with 100 cc normal saline is injected intravenously.

Category

Prevention

2

Description

Intervention group: 20 minutes before surgery ending, about 1g of acetaminophen with 100 cc normal saline is injected intravenously.

Category

Prevention

3

Description

Intervention group: 20 minutes before surgery ending, about 3 mg/kg of aminophylline with 100 cc normal saline is injected intravenously

Category

Prevention

4

Description

Control group: 20 minutes before surgery ending, 100 cc normal saline is injected intravenously.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz hospital

Full name of responsible person

Darioush Moradi Farsani

Street address

Modares St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mozhgan Mortazavi

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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

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

Iman Nikkhoo

Position

Resident

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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Position
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Latest degree
Medical doctor
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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 of the present study are provided by the relevant professor and in the case of publishing new and related studies are provided

When the data will become available and for how long

Following the publication of the article in an international journal, the data will be accessible

To whom data/document is available

Residents of anesthesiology who have a new proposal in this regard with the similar professor

Under which criteria data/document could be used

Only for publication of a new article with the relevant professor

From where data/document is obtainable

With the relevant anesthesiologist

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

Following a call or an email to the relevant professor

Comments