Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Isfehan
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

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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
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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
Anesthesiology

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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 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