Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of administration effects of intravenous acetaminophen on postoperative pain, nausea and sedation score in vitroretinal surgery with generall anesthesia

Protocol summary

Summary

Pain is one of the most important complications of surgeries. Pain increases complications, recovery time and costs. This study evaluates the preemptive effect of intravenous acetaminophen to control pain, nausea, vomiting, shivering in patients undergoing viteroretinal surgery with general anesthesia. This study evaluated 83 patients referred to the Farabi hospital in 1392. Inclusion criteria was age between 18 to 70 years. Exclusion criteria were opioid use within past 48 hours and neurologic diseases. Patients were randomly divided into 3 groups: Control group (41 patients) received 100 milliliter of normal saline as placebo on 20 minutes before surgery and 20 minutes prior to the end of the surgery. Preemptive group (21 patients) received 15 milligram/ kilogram of acetaminophen in 100 milliliter normal saline 20 minutes before surgery and 100 milliliter normal saline 20 minutes before the operation ending. Preventive group (21 patients) received 100 milliliter normal saline intravenously 20 minutes before surgery and 15 milligram/ kilogram acetaminophen in 100 milliliter normal saline 20 minutes before end of surgery. Pain scores in recovery, 2 and 4 hours after surgery in the control group were significantly higher than the other two groups. Twenty four hours after surgery, pain scores were not significantly different in the 2 groups. Analgesics consumption was significantly greater in the control group. Nausea, vomiting and shivering were not significantly different between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311139213N3**

Registration date: **2014-05-12, 1393/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-12, 1393/02/22

Registrant information

Name

Jalil Makarem

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1576

Email address

j-makarem@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of administration effects of intravenous acetaminophen on postoperative pain, nausea and sedation score in vitroretinal surgery with generall

anesthesia

Public title
Evaluation of preemptive effects of intravenous acetaminophe in viteroretinal surgery
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: Age between 18 to 70 years exclusion criteria: opioid use within past 48 hours; psychological and neurologic disease; sever heart disease; sever liver disease; sever kidney disease; hematologic disease; metabolic and physical disease; history of chronic pain;
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **83**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran university of medical sciences
Street address
Ghods street, keshavars boulevard
City
Tehran
Postal code
Approval date
2013-09-28, 1392/07/06
Ethics committee reference number
1427 / 130 / 92 / ص

Health conditions studied

1

Description of health condition studied
Vitreoretinal surgery
ICD-10 code
H35
ICD-10 code description
Other retinal disorders

Primary outcomes

1

Description
pain
Timepoint
recovery, 2h after surgery.4h after surgery.24h after surgery
Method of measurement
Pain from 1 to 10 based on VRS score will be recorded

Secondary outcomes

1

Description
nausa
Timepoint
ricovery, 2h after surgery,4 hour after surgery, 24h surgery
Method of measurement
Its presence or absence is recorded

2

Description
vomit
Timepoint
ricovery, 2h after surgery,4 hour after surgery, 24h surgery
Method of measurement
Its presence or absence is recorded

3

Description
shivering
Timepoint
recovery
Method of measurement
Its presence or absence is recorded

Intervention groups

1

Description
Control group (41 patients) received 100 milliliter of normal saline as placebo on 20 minutes before surgery and 20 minutes prior to the end of the surgery.
Category
Placebo

2

Description
Preemptive group (21 patients) received 15 milligram/ kilogram of acetaminophen in 100 milliliter normal saline 20 minutes before surgery and 100 milliliter normal saline 20 minutes before the operation ending
Category
Treatment - Drugs

3

Description
Preventive group (21 patients) received 100 milliliter normal saline intravenously 20 minutes before surgery and 15 milligram/ kilogram acetaminophen in 100 milliliter normal saline 20 minutes before end of surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Jalil Makarem, MD
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Jalil Makarem, MD
Street address
Poor sina street, 16th Azar street, Enqelab squre
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Jalil Makarem, MD
Position
Professor of anesthesiology
Other areas of specialty/work
Street address
Anesthesiology group, Emam khomeini hospital, Keshavars boulevard
City
Tehran
Postal code
Phone
+98 21 61190
Fax
Email
j.makarem@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Jalil Makarem, MD
Position
professor of aneshtesiology
Other areas of specialty/work
Street address
Anesthesiology group, Emam khomeini hospital, Keshavars boulevard
City
Tehran
Postal code
Phone
+98 21 61190
Fax
Email
j-makarem@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Jalil Makarem, MD
Position
professor of anesthesiology
Other areas of specialty/work
Street address
Anesthesiology group, Emam khomeini hospital,

Keshavars boulevard

City

Tehran

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty