

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

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

anesthesia

Public title

Evaluation of preemptive effects of intravenous acetaminophen in vitreoretinal 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; severe heart disease; severe liver disease; severe 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

nausea

Timepoint

recovery, 2h after surgery, 4 hour after surgery, 24h surgery

Method of measurement

Its presence or absence is recorded

2

Description

vomit

Timepoint

recovery, 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 square

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Tehran University of Medical Sciences

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professor of anesthesiology

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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