

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison the effects and complications of paracetamol versus fentanyl for postoperative pain , and patient satisfaction after cataract surgery under topical anesthesia in Farabi Eye Hospital Tehran, Iran in 2011-2012

Protocol summary

Summary

Cataract surgery is one of the most common types of eye surgeries performed around the world. Despite recent advantages in this procedure, post-operative pain management remains a significant problem. Acetaminophen is routinely used for controlling post-operative pain in several types of ocular surgery such as pan retinal photocoagulation, photorefractive keratotomy and cataract surgery and obtained promising results. To our knowledge, the comparison between Acetaminophen and fentanyl effect in reducing pain following cataract surgery has not been made yet, therefore this study was designed and conducted for filling this knowledge gap. Methods: A double-blinded randomized clinical trial was initiated to compare the effect of paracetamol and fentanyl for post-operative pain management in cataract surgery in Farabi hospital in Tehran, Iran between 2011 and 2012. A total of 160 patients were enrolled and randomly assigned to receive either 15 mg/kg paracetamol(max: 1gr paracetamol in100 cc normal saline) or fentanyl (1 µg/kg in 100 cc normal saline). All participants were given ringer's lactate solution (250 cc), midazolam (0.015mg/kg) and tetracaine (2 drops in each eyes with interval of 5 minutes). At the end of study patients' pain, anxiety and satisfaction was assessed by a single anesthesiologist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120511676N1**

Registration date: **2013-03-04, 1391/12/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-04, 1391/12/14

Registrant information

Name

Abbas Ostadalipour

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-02-18, 1391/11/30

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects and complications of paracetamol versus fentanyl for postoperative pain , and patient satisfaction after cataract surgery under topical anesthesia in Farabi Eye Hospital Tehran, Iran in 2011-2012

Public title

Comparison the effects and complications of

paracetamol versus fentanyl for postoperative pain , patient satisfaction after cataract surgery under topical anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: American Society of Anesthesiology=1-2; age=50-80 years and first time cataract surgery. Exclusion criteria: addiction; psychological diseases; anxiety; existence of previous pain; severe allergic reaction; uncontrolled hepatic, renal and cardiovascular disease; neurologic disease; uncontrolled Diabetes Mellitus disease and analgesic and sedative usage.

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

N/A

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

tehran university medical science

Street address

Tehran University of Medical Sciences, Faculty of Medicine, Poursina Street, Tehran, Iran

City

tehran

Postal code

1417613151

Approval date

2013-01-15, 1391/10/26

Ethics committee reference number

22496/210/91/3

Health conditions studied

1

Description of health condition studied

sedation, complication, cataract

ICD-10 code

H25.0

ICD-10 code description

Senile incipient cataract Senile cataract: coronary cortical punctate Subcapsular polar senile cataract (anterior)(posterior) Water clefts

Primary outcomes

1

Description

Heart rate

Timepoint

Before sedation 3 times, 3 min after sedation 3 times

Method of measurement

Monitoring full parameter pyandehgan company

2

Description

Saturation arterial o2

Timepoint

Before sedation 3 times, 3 min after sedation 3 times

Method of measurement

Pulse oximetry

3

Description

Pain

Timepoint

Before sedation, recovery

Method of measurement

VAS score

4

Description

Mean arterial pressure

Timepoint

Before sedation 3 times, 3 min after sedation 3 times

Method of measurement

Monitoring full parameter pyandehgan company

5

Description

Satisfaction

Timepoint

At the recovery room

Method of measurement

Score 0-10, 0=absent satisfaction, 10= max satisfaction

Secondary outcomes

1

Description

Apnea
Timepoint
During surgery
Method of measurement
Respiratory rate = 0

2

Description
Arrhythmia
Timepoint
During surgery
Method of measurement
Cardiac monitoring full parameter poyandehgan company

3

Description
Nausea and vomiting
Timepoint
At the recovery room
Method of measurement
Observation

Intervention groups

1

Description
Group 1 or intervention group or p: all participants were given midazolam 0.015 mg/kg and tetracain eye drop 2 drops in each eyes with interval of 5 minutes. Administered paracetamol (15 mg/kg) 1 g /100 cc normal salin/in 20 min stat.
Category
Treatment - Drugs

2

Description
Group2 or control group or F : all participants were given midazolam 0.015 mg/kg and tetracain eye drop 2 drops in each eyes with interval of 5 minutes. Administered fentanyl (1 µg/kg) in 100 cc normal salin intravenous / in 20 min stat
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi hospital
Full name of responsible person
abbas ostadalipour, anesthesiologist, assistant professor
Street address
operation room Farabi hospital, south karegar, postal code 1336616351

City
tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Tehran University of Medical Sciences and Health Services
Full name of responsible person
Dr Akbar Fotouhi
Street address
Ghods st. Cross, Keshavarz Bv
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research, Tehran University of Medical Sciences and Health Services
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
maryam jamshidi
Position
Anesthesiologist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Tehran University of Medical Sciences

Full name of responsible person

Abbas Ostadalipour

Position

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Person responsible for updating data

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Full name of responsible person

Abbas Ostadalipour

Position

Anesthesiologist

Other areas of specialty/work**Street address**

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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