Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison between the effects of Acetaminophen and Dexmedetomidine infusion and normal saline on pain severity after cataract surgery an open label randomized controlled trial

Protocol summary

Study aim
Comparison between the effects of Acetaminophen and Dexmedetomidine infusion on pain severity after cataract surgery under complete venous sedation

Design
Three-arm parallel groups phase 3 randomized trial, single-blind, on 135 patients, sealedenvelope website was used for random allocation

Settings and conduct
All patients were monitored with electrocardiography, pulse oximetry, and non-invasive blood pressure monitoring. During the procedure, vital signs were recorded by a trained nurse in certain time-points. Pain intensity was evaluated and recorded based on Visual Analog Scale. Presence of nausea and vomiting after surgery was asked and recorded. The amount and time for the first narcotics request was recorded for each patient. side effects of medications and the satisfaction of ophthalmologists from the patient sedation during the operation was recorded. also, the length of stay in the recovery room was recorded. The study was performed at Feyz Ophthalmology Hospital in Isfahan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- A I or II physical health score according to the classification of the American Society of Anesthesiologists 2- Patient consent to participate in the study 3- age between 50 to 80 years old 4- being candidate for cataract surgery Exclusion criteria: 1- contraindication of dexmedetomidine or acetaminophen 2- Allergies to any of the drugs used in the trial 3- Blood coagulation problems 4- Altered mental status 5- Severe cardiovascular diseases 6- Chronic obstructive pulmonary disease

Intervention groups
In group A, acetaminophen was infused at a dose of 15 mg/kg within the first 15 minutes of surgery. In group B, dexmedetomidine was infused at a dose of 0.5 µgr/kg within the first 15 minutes of surgery. In group C, only the infusion of normal saline was performed.

Main outcome variables
Pain severity; surgeon satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190208042654N4**
Registration date: **2021-04-12, 1400/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-12, 1400/01/23**
Update count: **0**

Registration date
2021-04-12, 1400/01/23

Registrant information

Name
Vahid Mansouri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-05, 1399/08/15

Expected recruitment end date
2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effects of Acetaminophen and Dexmedetomidine infusion and normal saline on pain severity after cataract surgery an open label randomized controlled trial

Public title

The effect of acetaminophen and dexmedetomidine infusion on the severity of cataract surgery pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ⅰor Ⅱ physical health score according to the classification of the American Society of Anesthesiologists Candidate for cataracts surgery Age between 50 to 80 years old Patient consent to participate in the study

Exclusion criteria:

patient contraindication of dexmedetomidine or acetaminophen Allergies to any of the drugs used in the trial Blood coagulation problems Altered mental status Severe cardiovascular diseases chronic obstructive pulmonary disease

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

The study population was selected on a consecutive basis. For the randomization of the participants, first, the principal investigator used the “Sealedenvelope” website to create blocks containing 9 individuals, containing three participants for each of three groups. Every participant had a unique code consisting of two letters and one number. This generated list remained confidential for participants, clinicians who enrolled the patients in the study, clinicians who injected the drugs and data analyzer. Patients have entered the study groups (A, B and C) according to the generated list, after a full explanation of the study process and obtaining written consent.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind study, where physicians and patients were aware of study groups and only the statistical analyzer was blind for treatment groups. Each group was assigned with A or B or C, which makes the analyzer blind for the treatment group.

Placebo

Not used

Assignment

Parallel

Other design features

This randomized controlled clinical trial had an equal allocation ratio for two groups of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

IR.MUI.MED.REC.1396.3.314

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

E08.36

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic cataract

Primary outcomes

1

Description

Pain severity

Timepoint

immediately after surgery, 2 hours, 4 hours, and 6 hours after moving to the recovery room and then at the time of discharge

Method of measurement

Based on Visual Analog Scale (VAS) on a scale from 0 to 10

2

Description
Surgeon Satisfaction from sedation
Timepoint
After surgery
Method of measurement
Levels of satisfaction were defined as Excellent (The patient's sedation and cooperation were complete), Good (The patient cooperated despite unwanted and minor eye movements) and poor (There was a lot of unwanted eye movement during the operation and the patient did not cooperate).

Secondary outcomes

1

Description
Heart Rate
Timepoint
the start of surgery, 5, 10 and 15 minutes after starting of surgery, then at the beginning of recovery, 20, 40, 60 minutes after starting of recovery
Method of measurement
Through patient monitoring device or by taking a carotid pulse

2

Description
Respiratory rate
Timepoint
the start of surgery, 5, 10 and 15 minutes after starting of surgery, then at the beginning of recovery, 20, 40, 60 minutes after starting of recovery
Method of measurement
Counting the respiratory cycles in one minute

3

Description
Venous Oxygen Saturation
Timepoint
the start of surgery, 5, 10 and 15 minutes after starting of surgery, then at the beginning of recovery, 20, 40, 60 minutes after starting of recovery
Method of measurement
Pulse oximetry

4

Description
Systolic Blood Pressure
Timepoint
the start of surgery, 5, 10 and 15 minutes after starting of surgery, then at the beginning of recovery, 20, 40, 60 minutes after starting of recovery
Method of measurement
non-invasive blood pressure (NIBP) monitoring

5

Description
Diastolic Blood Pressure
Timepoint
the start of surgery, 5, 10 and 15 minutes after starting of surgery, then at the beginning of recovery, 20, 40, 60 minutes after starting of recovery
Method of measurement
non-invasive blood pressure (NIBP) monitoring

Intervention groups

1

Description
Intervention group 1: infusion of Acetaminophen IV at a dose of 15 mg/kg within the first 15 minutes of surgery, slowly in total volume of 100 ml
Category
Treatment - Drugs

2

Description
Intervention group 2: infusion of dexmedetomidine IV at a dose of 0.5 µgr/kg within the first 15 minutes of surgery, slowly in total volume of 100 ml
Category
Treatment - Drugs

3

Description
Control group: Injection of 100 ml of normal saline in the first 15 minutes of surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feyz Ophthalmology Hospital
Full name of responsible person
Dr Dariush Moradi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
396314
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
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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available