

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The study effect of intravenous acetaminophen in comparison with fentanyl on pain severity after Cataract surgery

Protocol summary

Study aim

Effect of intravenous acetaminophen and fentanyl on reduction of pain after cataract surgery

Design

Double blind randomized clinical trials

Settings and conduct

Patients with cataract surgery who will be referred to Farshchian Hospital in Hamadan in 2018.

Participants/Inclusion and exclusion criteria

Inclusion criteria: (a) patients with class 1 or 2 according to the American Society of Anesthesiology scoring criteria; (b) age of 25-55 years; (c) no history of psychotropic or opium drugs consumption. Exclusion criteria: (a) history of allergy to the drugs used in the plan; (b) disagreement with the patient's plan.

Intervention groups

50 patients receive 10 mg / kg acetaminophen per 100 ml of ringer serum for 20 minutes, and 50 patients will receive 1 microgram / kg intravenous 2 minutes before anesthesia induction.

Main outcome variables

Primary outcome: (a) severity of pain 1, 6, 12, 18, and 24 hours after surgery using visual analog scale (VAS); (b) opium dose (mg) usage 1, 6, 12, 18, and 24 hours after surgery; (c) hemodynamic status (blood pressure, heart rate) 1, 6, 12, 18, and 24 hours after surgery after surgery. Secondary outcome: (a) systemic side effects (nausea and vomiting); (b) urinary retention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120430009597N4**

Registration date: **2018-07-07, 1397/04/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-07, 1397/04/16**

Update count: **0**

Registration date

2018-07-07, 1397/04/16

Registrant information

Name

Seyed Mohamad Zolhavarieh

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0020

Email address

sm.zolhavarieh@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study effect of intravenous acetaminophen in comparison with fentanyl on pain severity after Cataract surgery

Public title

The study effect of intravenous acetaminophen in comparison with fentanyl on pain severity after Cataract surgery in patients referring to Farshchian Hospital of Hamedan

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with class 1 or 2 according to the American Society of Anesthesiology scoring criteria no history of psychotropic or opium drugs consumption age of 25-55 years.

Exclusion criteria:

History of allergy to drugs used in the project Failure to agree to the project by the patient

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample allocated to each of the two groups and the control block will be Block random permutation, with the fentanyl group (code A) and the acetaminophen group (code B) considered. Using random blocks of ABABBA 6 randomly selected samples are allocated to treatments. In this sample, the first person in the treatment group A is the second person in treatment B, the third in treatment A, the fourth in treatment B, the fifth in treatment B and the person The sixth treatment group A will receive the fentanyl group and the acetaminophen group. And this will continue to number of samples in groups. The next block will be as follows. AABABA, BABBAA, ABBABA, BBABAA, BABABA, BBABAA, ABABBA, BAAABB, BAABBA, ABBAB, BAABBA, BABAAB, BABABA, BBBAAA, BABAAB, ABBAAB.

Blinding (investigator's opinion)

Double blinded

Blinding description

A randomized, double blind clinical trial that the main author and patients are unaware of drugs groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.UMSHA.REC.1397.097

Health conditions studied

1

Description of health condition studied

Cataract surgery

ICD-10 code

H59.9

ICD-10 code description

Postprocedural disorder of eye and adnexa, unspecified

Primary outcomes

1

Description

Pain severity

Timepoint

1, 6, 12, 18, and 24 hours after surgery

Method of measurement

Visual Analog Scale (VAS)

2

Description

Opium dose (mg) usage

Timepoint

1, 6, 12, 18, and 24 hours after surgery

Method of measurement

Medical record

3

Description

Hemodynamic status (blood pressure, heart rate)

Timepoint

1, 6, 12, 18, and 24 hours after surgery

Method of measurement

Physical examination

Secondary outcomes

1

Description

Nausea

Timepoint

2 hours after surgery

Method of measurement

Questionnaire

2

Description

Vomiting

Timepoint

2 hours after surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: 50 patients in the fentanyl group will receive 1 microgram / kg intravenous 2 minutes before anesthesia induction.

Category

Treatment - Drugs

2

Description

Intervention group: In 50 patients, 10 mg / kg of acetaminophen was infused in 100 ml of ringer serum for 20 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Seyed Mohammad Zolhavarieh

Street address

Shahid Fahmidah Street - Farshchian Hospital

City

Hamadan

Province

Hamadan

Postal code

6517953371

Phone

+98 81 1838 0749

Email

dsmbzolzohavarieh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. saeid bashirian

Street address

Vice-chancellor of Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

38381035

Phone

+98 81 3838 1035

Email

s-bashirian@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Mohammad zolhavarieh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Beheshti Hospital, Eram Blv.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0283

Email

dsmbzolzohavarieh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Zolhavarieh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0283

Email

dsmbzolzohavarieh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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