# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Jun 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)

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**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
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## Sponsors / Funding sources

### 1

**Sponsor**
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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**
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## Person responsible for scientific inquiries

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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