# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparative study of the effect of intravenous Dexmedotomidian and Fentanyl in comparison with Midazolam and Sufentanyl on pain severity, surgen consent, patient sedation, hemodynamic status after cataract surgery

## Protocol summary

**Study aim**

Comparison of the effect of intravenous dexmedetomidine and fentanyl with intravenous midazolam and sufentanil on patient pain intensity, surgeon satisfaction, patient sedation, and hemodynamic status after cataract surgery.

**Design**

A controlled, double-blind, randomized clinical trial of 80 patients, phase 3, block randomization according to the website. https://www.sealedenvelope.com/simple-randomiser/v1/lists

**Settings and conduct**

The study will be conducted in Farshchian Sina Hospital in Hamedan. 2 drops of 0.5% tetracaine are instilled in the eyes of all patients. The surgeon and the patient are blind. During surgery and intervention, the patient's vital signs such as: blood pressure, heart rate and oxygen saturation level are measured. In the intervention group, 2 micrograms/kg per hour of dexmedetomidine and 1 cc of fentanyl are injected intravenously. In the control group, 1 mg of midazolam and 1 cc of sufentanil are injected.Surgery in both groups is performed by phyco-emulsification. After transfer of patients to recovery, the vital signs checke. Using visual pain scale (VAS). The surgeon satisfaction is asked by interview . The hemodynamic status of the patients and the level of sedation are recorded with the Ramsay scale.

**Participants/Inclusion and exclusion criteria**

ASA1&2 cataract surgery by phacoemulsification

**Intervention groups**

In the intervention group, the use of intravenous dexmedetomidine and fentanyl drugs. Sufentanil and midazolam drugs are used in the control group.

**Main outcome variables**

Patient's pain, surgeon's satisfaction, patient's hemodynamic status, patient's sedation status

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20231231060584N1**
Registration date: **2024-01-27, 1402/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-27, 1402/11/07**
Update count: **0**

**Registration date**

2024-01-27, 1402/11/07

**Registrant information**

**Name**

Zahra Ataei Barazandeh

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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+98 81 3838 5389

**Email address**

za.ataeibarazandeh@edu.umsha.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-01-21, 1402/11/01

**Expected recruitment end date**

2024-03-18, 1402/12/28

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparative study of the effect of intravenous Dexmedotomidian and Fentanyl in comparison with Midazolam and Sufentanyl on pain severity, surgen consent, patient sedation, hemodynamic status after cataract surgery

**Public title**
study of the effect of Dexmedetomidine and Fentanil on pain severity and hemodynamic status on catarct surgeries patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
ASA 1&2 not use of drugs and strong painkillers chronically cataract surgery by phacoemulsification
**Exclusion criteria:**
ASA 3 use of another drug inside of study drugs
**Age**
From **45 years** old to **85 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The research units are placed in two intervention and control groups with easy sampling and random allocation. The random method is block random. The random sequence and block are extracted from the following website. https://www.sealedenvelope.com/simple-randomiser/v1/lists
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The participants in the study (patients) do not know in which group 1 or 2 they are. The surgeon does not know which group 1 or 2 the patient will be operated on.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Hamedan University of Medical Sciences
**Street address**
Mirzadeh Eshghi Ave, Farshchian Sina Hospital
**City**
Hamedan
**Province**
Hamadan
**Postal code**
6516783736
**Approval date**
2023-12-30, 1402/10/09
**Ethics committee reference number**
IR.UMSHA.REC.1402.623

## Health conditions studied

**1**

**Description of health condition studied**
Cataract surgery by phacoemulsification
**ICD-10 code**
H25
**ICD-10 code description**
Age-related cataract

## Primary outcomes

**1**

**Description**
pain severity
**Timepoint**
0-30-60 minutes after surgery
**Method of measurement**
VAS scale

## Secondary outcomes

**1**

**Description**
patient sedation
**Timepoint**
0-30-6- minutes after surgery
**Method of measurement**
RAMSEY scale

## Intervention groups

**1**

**Description**
Intervention group: Dexmedetomidine 1 microgram/kg and Fentanyl 1 mg/kg are used intravenously during

surgery. (Both drugs must be injected on each patient.)

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Sufentanil 1 mg/kg and midazolam 1 mg/kg are used as intravenous injections during surgery. (Both drugs must be injected to each patient.)

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Farshchian Sina Hospital, eye operating room

**Full name of responsible person**

Behzad Imani

**Street address**

Pastor Crossroad, Mirzadeh Eshghi st. Farshchian Sina Hospital

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behzadiman@yahoo.com

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http://www.umsha.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Behzad Imani

**Street address**

Shahid Fahmide Blvd, Hamedan University of Medical Science

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**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**

Behzad Imani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**
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**Position**
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**Latest degree**
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**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
It will be available after the end of sampling.
**When the data will become available and for how long**
It will be available after the end of sampling.
**To whom data/document is available**
It will be available after the end of sampling.
**Under which criteria data/document could be used**
It will be available after the end of sampling.
**From where data/document is obtainable**
It will be available after the end of sampling.
**What processes are involved for a request to access data/document**
It will be available after the end of sampling.
**Comments**