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

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Iran (Islamic Republic of)

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+98 81 3838 5389

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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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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