

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the Effectiveness of Nasal fentanyl vs. Intravenous (IV) fentanyl in anesthesia in patients with cataract surgery

Protocol summary

Study aim

Comparison of the Effectiveness of Nasal fentanyl vs. Intravenous fentanyl in analgesia in patients with cataract surgery

Design

Randomised, superiority, parallel, three-way blind, randomized, on 90 patients. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct

This study was a three-course study conducted at the Feyz Isfahan Medical-Educational Center. The available (easy) sampling method and simple randomization method were used using Random allocation software. The patient surgeon and the person collecting the information were unaware of the patients' drug grouping

Participants/Inclusion and exclusion criteria

Candidates for cataract surgery in adults Criteria for not entering the study: history of allergy or allergic reaction to any of the medications of diet therapy, head injury, high intraocular or intracranial pressure, high-risk cardiovascular disease, hypertension, severe respiratory disease, liver disease, advanced Epilepsy or history of seizures, neurological disorders, tumors or brain metastases, use of any painkillers and anesthesia precursors, chronic pain syndromes, people who are not satisfied with participating in this study

Intervention groups

in Intravenous fentanyl group, (1.5 mg / kg with a volume of 2 cc fentanyl) is prescribed intravenously and 2 cc of distilled water in the nose. In the nasal fentanyl group, 2cc of fentanyl, 1.5 mg / kg intranasally, and 2 cc of distilled water are administered intravenously.

Main outcome variables

Intravenous fentanyl! Intranasal fentanyl

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200605047662N1**

Registration date: **2020-06-09, 1399/03/20**

Registration timing: **retrospective**

Last update: **2020-06-09, 1399/03/20**

Update count: **0**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name

Hamed Norouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3422 2149

Email address

hamednorouzi7337@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-19, 1395/12/29

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

2017-03-19, 1395/12/29

Actual recruitment end date

2019-03-19, 1397/12/28

Trial completion date

2019-03-19, 1397/12/28

Scientific title

Comparison of the Effectiveness of Nasal fentanyl vs. Intravenous (IV) fentanyl in anesthesia in patients with cataract surgery

Public title

Effect of Nasal fentanyl in patients with cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

More than 18 years old American Society of Anesthesiologists Classification (ASA) 1 or 2 Candidate for cataract surgery by Phacoemulsification method

Exclusion criteria:

History of any allergic reaction to any of the treatment regimens History of head injury, high intraocular or intracranial pressure, high-risk for cardiovascular disease, severe respiratory disease, liver disease, advanced epilepsy or seizure history, neurological disorder, tumor or brain metastasis Use of any anesthetics in last day Chronic pain syndromes

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The 45 pieces of paper that were written on it A and the other 45 pieces that were written B (a total of 90 pieces) are folded into a non-transparent bag. Then 30 minute before the operation, one of the pieces were selected randomly by a person who does not know about the details. In case of A patient categorized as the intra-venous fentanyl group, and in case of B, it belongs to the nasal fentanyl group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In 30 minute before the surgery, the patient was selected to A and B group by using pieces of paper in a non-transparent bag by person who did not know about the details. The patient didn't know about the grouping. The patient was taken to the operating room and the surgeon and staff of the relevant room did not know about the grouping. After the surgery, the surgeon's satisfaction was recorded by the person who did not know about the grouping. The patient transferred to the recovery room, where was evaluated by the person who had no information about the grouping and the patient's information was recorded. In the operating room, only the person who performed the lottery knew about the grouping, and this person had intravenous and nasal fentanyl in addition to distilled water in the form of nasal and intravenous form, and he was the only person who

knew which fentanyl and which distilled water were also.

This person was not present in any other part of the patient's information collection and evaluation

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of medical sciences., Azadegan street., Hezar-Jarib blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.MUI.MED.REC.1398.127

Health conditions studied**1****Description of health condition studied**

Cataract

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes**1****Description**

Relaxation level during surgery

Timepoint

After surgery, In Recovery room

Method of measurement

Ramsay Sedation Scale questionnaire

2**Description**

Satisfaction of the surgeon

Timepoint

After surgery
Method of measurement
Visual Analogue Scale questionnaire

3

Description

Satisfaction of the patient

Timepoint

After surgery

Method of measurement

Visual Analogue Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients after grouping, if they were in the nasal fentanyl group, were given a single dose of intranasal fentanyl (1 mg / kg with a volume of 2 cc), 10 minutes before the surgery and at the beginning of surgery, Distilled water (2 cc) were prescribed Intravenously

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients after grouping, if they were in the intra-venous fentanyl group, were given a single dose of intranasal Distilled water (2 cc) ,10 minutes before the surgery and at the beginning of surgery, fentanyl (1 mg / kg with a volume of 2 cc) were prescribed Intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital

Full name of responsible person

Hamed Norozi

Street address

Hezar-Jarib street., University of medical sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

hamednorouzi7337@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Street address

Hezar-Jarib Street., University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

Hamednorouzi7337@gmail.com

Grant name

Grant code / Reference number

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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamed Norouzi

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Hezar-Jarib street., University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code
8174673461
Phone
+98 31 3792 7654
Email
Hamednorouzi7337@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamed Norozi
Position
Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Hezar-Jarib., University of Medical Sciences
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 7654
Email
Hamednorouzi7337@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamed Norozi

Position
Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Hezar-Jarib., University of Medical Sciences
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 7654
Email
hamednorouzi7337@gmail.com

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