Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect of ketorolac and intravenous lidocaine on fentanyl-induced cough in patients undergoing elective surgery: a Double-blind clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate the efficacy of ketorolac in inhibiting the fentanyl induced cough of before induction of general anesthesia and to compare its effectiveness with intravenous lidocaine so that it can be used as an alternative when lidocaine is contraindicated.

Design

prospective randomized controlled trial with control group, 3 arm parallel groups, double-blind, randomized, phase 3 on 210 patients. Excel software rand function was used for randomization.

Settings and conduct

in Firoozgar and Rasool Akram Hospital Eligible patients are randomly assigned to one of three groups receiving intravenous lidocaine, ketorolac, or normal saline.Depending on the group of each patient, drugs of the same volume will be injected and then receive intravenous fentanyl and the incidence and severity of the cough will be recorded.

Participants/Inclusion and exclusion criteria

The patients are 18 to 60 years old, with any gender and with ASA 1 or 2, who referred to Firoozgar and Hazrat Rasool Akram hospitals in the period of April 2022 to June 2022 and are candidates for elective surgery that lasts more than an hour. Exclusion criteria are: preoperative pulmonary emphysema, bronchial asthma, history of upper respiratory tract infection over the past 2 weeks, smoking, history of hypertension and coronary artery disease, chronic cough, hypertension Inside the eye, brain or abdomen, etc...

Intervention groups

Depending on the group of patients, 0.5 mg / kg ketorolac, 1 mg / kg lidocaine or normal saline is injected intravenously in the same syringe with the same volume within 15 seconds. After 3 minutes of drug injection, all patients will receive 3mcg / kg intravenous fentanyl within 3 seconds. The occurrence and severity of cough will be recorded.

Main outcome variables

Cough, Cough intensity, Cough onset time, Heart rate, Arterial blood pressure, Arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220102053599N1**
Registration date: **2022-06-25, 1401/04/04**
Registration timing: **retrospective**

Last update: **2022-06-25, 1401/04/04**
Update count: **0**

Registration date

2022-06-25, 1401/04/04

Registrant information

Name

Nasrin Nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2326

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of ketorolac and intravenous lidocaine on fentanyl-induced cough in patients undergoing elective surgery: a Double-blind clinical trial

Public title
Comparison of the effect of ketorolac and intravenous lidocaine on fentanyl-induced cough in surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
aged 18 to 60 years, with and with, who any gender ASA 1 or 2 referred to Firoozgar and Hazrat Rasul-e Akram hospitals and are candidates for elective surgery that lasts more than an hour in the period of April 2022 to June 2022
Exclusion criteria:
Preoperative pulmonary emphysema Bronchial asthma History of upper respiratory infection during the last 2 weeks Smoking Hypertension Coronary artery disease Has a chronic cough that makes it difficult to diagnose fentanyl-induced cough High pressure inside the eyes, brain or abdomen Taking anti-anxiety and anti-depressant drugs before surgery Taking anti-cough medicines (codeine, dextromethorphan, baclofen, steroids or bronchodilators) during the last week BMI above 28 kg/m2 History of chronic opioid use Taking cough medicines (ACEI & ABR) History of GERD or peptic ulcer History of kidney or liver disease Pregnancy or breastfeeding Known allergy to fentanyl or ketorolac G6PD deficiency disease High risk of GIB Patient reluctance
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **210**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients randomly (using the computer random numbers method which, the numbers 1 to 3 are entered into the computer and by pressing the button to create a random number, a number between 1, 2 and 3 is generated that will indicate the patient group) enter In one of the 3 groups receiving intravenous lidocaine, ketorolac or normal saline are included as placebo until the sample volume is completed.
Blinding (investigator's opinion)
Double blinded
Blinding description
After selecting patients to enter the study, patients are randomly assigned to one of the 3 groups receiving intravenous lidocaine, ketorolac or normal saline as a placebo to complete the sample size. These individuals are in groups A, B, C The group of each patient is written in a sealed envelope and is given to each person in the unit before the operating room by the researcher and the patient enters the operating room with it. The drugs are prepared in similar 5 cc syringes by an anesthetist of the recovery unit who has no role in patient care and the names of the groups are labeled on them. Upon entering the room, the anesthesiologist in the room delivers the medication to the assistant along with the other anesthetics to induce anesthesia. The patient enters the study after obtaining consent and according to the information given about the study, but does not know about the injectable drug. In this way, patients and drug injecting assistants and cough observers (who are responsible for recording data) will be unaware of prescription drugs and study grouping
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Unit 1, No. 53, Hojjatdoost St., Naderi St., Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1416635491
Approval date
2021-12-07, 1400/09/16
Ethics committee reference number
IR.IUMS.FMD.REC.1400.538

Health conditions studied

1

Description of health condition studied
Fentanyl induced Cough
ICD-10 code
R05
ICD-10 code description
Cough

Primary outcomes

1

Description
cough
Timepoint
Within 90 seconds of fentanyl injection
Method of measurement
observation

Secondary outcomes

1

Description
Cough Intensity
Timepoint
Within 90 seconds of fentanyl injection
Method of measurement
Observation

2

Description
Cough start time
Timepoint
Within 90 seconds of fentanyl injection
Method of measurement
Stopwatch

Intervention groups

1

Description
Intervention group No.1: The group receiving 1mg / kg intravenous lidocaine 2%(100mg/5ml, Caspian,Tamin,RASHT.IRAN) 3 minutes before intravenous fentanyl (fentanyl citrate,0.5mg/10ml ,Aburaihan Co.IRAN)
Category
Treatment - Drugs

2

Description
Intervention group No.2: The group receiving intravenous ketorolac 0.5 mg / kg (Ketorolac-EXIR, 30mg/ml, EXIR.IRAN) 3 minutes before intravenous fentanyl (fentanyl citrate,0.5mg/10ml ,Aburaihan Co.IRAN)
Category
Treatment - Drugs

3

Description
Control group: A group receiving the same amount of intravenous saline as the first and second control groups three minutes before intravenous fentanyl.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasul-e Akram Hpspital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran University of Medical Sciences

Proportion provided by this source
50

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
Iran University of Medical Sciences
Full name of responsible person
Sara Tahzibi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to the publication of the results completely, there is no need to publish the research data separately. Also, in this study, consent is not obtained to use patients' data in other studies, which is another reason that justifies this issue.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All the data of this research, including variables and primary and secondary consequences, etc., can be shared without naming people.

When the data will become available and for how long

From the time the results are published, all information will be available without time limit.

To whom data/document is available

Information will be available to all academic and non-academic researchers in any field.

Under which criteria data/document could be used

Patients' data will not be published separately, and other studies must use a code of ethics to use this information and, after consulting the contributors to the present study, obtain their consent again.

From where data/document is obtainable

Sara Tahzibi Contact No. : 00989192419907 E-mail: Sara.tahzbi@gmail.com

What processes are involved for a request to access data/document

Obtaining ethics - Obtaining written permission from the collectors of the present study - Obtaining re-consent from the patients present in this study to use their information

Comments