Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of dexmedetomidine and lidocaine on fentanyl induced cough in patients undergoing elective surgery

Protocol summary

Study aim
Comparison of the effect of dexmedetomidine and lidocaine on cough caused by fentanyl injection in patients undergoing elective surgery in Shahid Mohammadi Hospital, Bandar Abbas

Design
Prospective, double-blind, single-group clinical trial, data are analyzed by SPSS software using Chi-square and t-test.

Settings and conduct
This study will be performed as a prospective clinical trial on patients who will refer to Shahid Mohammadi Hospital for elective surgery in 1400. Patients are included in the study according to the inclusion criteria and written consent is obtained from all of them to participate in the study. Then all the desired variables including age, sex, height and weight of patients will be collected. Patients are then randomly divided into three groups according to a random allocation table. To blind patients, the first group will receive the equivalent volume of lidocaine from normal saline solution 90 seconds before prodrug and the second and third group patients will receive 10 ml of isotonic saline 10 minutes before prodrug administration. After administration of these drugs, all patients received 2 µg / kg fentanyl from a 50 µg / ml vial (Caspian Drug Company / Rasht / Iran) intravenously for 5 seconds and 2 minutes after fentanyl injection, patients were exposed to (Yes / No) and we will examine the severity of cough (2-1 mild / 5-3 moderate /> severe 5).

Participants/Inclusion and exclusion criteria
Patients aged 18 to 65 years with ASA I and II undergoing elective surgery in 1400.

Intervention groups
Comparison of the efficacy of lidocaine and dexmedetomidine

Main outcome variables
Cough intensity; Cough incidence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211023052848N1**
Registration date: **2021-11-17, 1400/08/26**
Registration timing: **prospective**

Last update: **2021-11-17, 1400/08/26**
Update count: **0**

Registration date
2021-11-17, 1400/08/26

Registrant information

Name
Fatemeh Taherzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 5343 3591

Email address
zhrkrdn@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-21, 1400/08/30

Expected recruitment end date
2021-12-21, 1400/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of dexmedetomidine and lidocaine on fentanyl induced cough in patients undergoing elective surgery

Public title
Comparison of the effect of dexmedetomidine and lidocaine on fentanyl induced cough

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients candidates for elective surgery taking fentanyl. Patients aged 18-65 years Informed consent

Exclusion criteria:
Patients taking fentanyl are not candidates for elective surgery. Patients receiving corticosteroids A person with a history of asthma and respiratory diseases in the previous 4 weeks A person with a history of allergies to fentanyl or dexmedetomidine Patients in need of emergency surgery

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **171**

Randomization (investigator's opinion)
Randomized

Randomization description
Epidemiologist download the random allocation software from http://random-allocation-software-inform.com,which this random sequence generation software in addition to randomization is able to generate random sequences in different ways.Simple randomization was done in each group through random allocation software (version 1.0.0) and entered the number of groups,sample size and group name into main windows icon,then a sequence of 171 cases(equal to sample size) was created using the Rnd function that the patients randomly and based on this random sequence table,enter to one of groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind patients, the first group will receive the equivalent volume of lidocaine from normal saline solution 90 seconds before the prodrug and the second and third group patients will receive 10 ml of isotonic salibene 10 minutes before the prodrug administration. All this information will be provided by an anesthesia assistant who does not know the grouping and how to inject the drugs. Because the patients are also unaware of the groups, the study is double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of University of Medical Sciences - School of Medicine

Street address
Imam Hossein Boulevard, Tohid Town

City
Bandarabbas

Province
Hormozgan

Postal code
7915865883

Approval date
2021-09-19, 1400/06/28

Ethics committee reference number
IR.HUMS.REC.1400.276

Health conditions studied

1

Description of health condition studied
fentanyl indeuced cough

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
incidence of cough

Timepoint
Evaluation of cough in patients candidates for elective surgery, two minutes after fentanyl injection

Method of measurement
Cough incidence questionnaire

2

Description
Intensity of cough

Timepoint
Evaluation of cough severity in patients candidates for elective surgery, two minutes after fentanyl injection

Method of measurement
Cough Intensity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Lidocaine: 1.5 mg / kg intravenously for 90 seconds before fentanyl injection
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group 2: Dexmedetomidine: 0.5 µg / kg solution of 10 cc of isotonic saline 10 minutes before anesthesia, by infusion
Category
Treatment - Drugs

3

Description
Control group: normal saline at a dose of 1.5 mg / kg for 90 seconds before fentanyl injection as infusion
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital, Bandar Abbas
Full name of responsible person
Fatemeh Taherzadeh
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North Mission, Sadeghieh Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas 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?
No
Title of funding source
Hormozgan 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
Bandare-abbas University of Medical Sciences
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Position
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Position

General Practitioner

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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

No - There is not 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