Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Oct 2026

Comparison of Lidocaine, Huffing Maneuver and combination of both in prevention fentanil induced cough before induction of anesthesia

Protocol summary

Study aim
To determine the effect of lidocaine and Huffing maneuver in preventing reflective cough after rapid fentanil injection

Design
Prospective randomized controlled clinical trial

Settings and conduct
400 Patients in the Namazi Hospital are randomly divided into four groups of each 100. 100 people are considered as control group. First intervention group: Patients receive 2 mg / kg lidocaine before injection of fentanil. Second intervention group: Huffing maneuver is performed for patients before injection of fentanil. Third intervention group: patients received 2 mg / kg lidocaine with Huffing maneuver . Fourth intervention group:Combined protocol (2 mg / kg lidocaine is injected one minute before fentanil injection and after 55 seconds, huffing maneuver is performed after a deep breath less than 5 seconds, and followed by fentanil 2.5 µg/kg and patients are checked every two minutes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 16 - 65 years old; elective surgery. Exclusion criteria: Asthma; Chronic cough; upper respiratory tract infection two weeks before surgery; smoking; steroid therapy;using bronchodilatorand ACE inhibitor.

Intervention groups
First intervention group: Patients receive 2 mg / kg lidocaine before injection of fentanil. Second intervention group: Huffing maneuver is performed before injection of fentanil. Third intervention group: Injection of 2 mg / kg lidocaine with Huffing maneuver on patients.

Main outcome variables
Existence or absence of cough reflex and also the severity of coughing are evaluated.1-2 coughs grade one, 3-4 coughs grade 2 and 5 and more than 5 coughs considered as grade 3.

General information

Reason for update
Due to the inconsistency recorded in the date of the Ethical approval code and Forgetting to correct the date, please correct the date.

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N74**
Registration date: **2018-03-09, 1396/12/18**
Registration timing: **prospective**

Last update: **2021-01-18, 1399/10/29**
Update count: **1**

Registration date
2018-03-09, 1396/12/18

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-15, 1396/12/24

Expected recruitment end date
2018-09-15, 1397/06/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of Lidocaine, Huffing Maneuver and combination of both in prevention fentanil induced cough before induction of anesthesia

Public title
The relation between Lidocaine and Huffing Maneuver in prevention of cough after fentanil injection

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age 16 - 65 years old, elective surgery
Exclusion criteria:
Asthma; Chronic cough, upper respiratory tract infection two weeks before surgery; smoking; steroid therapy;using bronchodilator and ACE inhibitor.

Age
From **16 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **400**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
only observer after intervention is blinded to the study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
7134844119

Approval date
2015-03-03, 1393/12/12

Ethics committee reference number
IR.SUMS.MED.RED.1394.61

Health conditions studied

1

Description of health condition studied
The relation between Lidocaine and Huffing Maneuver in prevention of cough after fentanil injection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cough reflect

Timepoint
2 minutes after fentanil injection

Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Control group:

Category
N/A

2

Description
Intervention group:

Category
Prevention

3

Description
Intervention group:

Category
Prevention

4

Description
Intervention group:

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Lale Dehghanpishe

Street address
Namazi Suare, Namazi Hospital

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Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Seed Basir Hashemi

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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Bagheri Baravati

Position
anesthesiology resident/physician

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Full name of responsible person
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Position
MS in English Teaching ,BS in Anesthesia/English Consultant

Latest degree
Master

Other areas of specialty/work
Others

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Web page address

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
It is against the policies of our center.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not 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
Not applicable

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable