Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of duration of injection time on the incidence and severity of fentanyl-induced cough (FIC)

Protocol summary

Study aim
The effect of duration of injection time on the incidence and severity of fentanyl-induced cough (FIC)

Design
This clinical trial will consist of three groups, double-blind, randomized, and parallel. Samples will be determined using Block Randomization method, Allocation Random Software and based on injection rate of 150 pcs. The numbers x≤50 will fall into the first group, 50˂x≤100 in the second group, and 100˂x≤150 into the third group. Patients will receive fentanyl over the course of 2–5 seconds in the first group, 15 seconds in the second group, and 30 seconds in the third group.

Settings and conduct
This double blind clinical trial study will be conducted on 150 patients with ASA1 candidates for elective surgery in Shahid Mohammadi hospital in Bandar Abbas. Patients will receive fentanyl over the course of 2–5 seconds in the first group, 15 seconds in the second group, and 30 seconds in the third group. Patients will not be aware of the duration of fentanyl injection. Information will be recorded in a special form by an experienced anesthesiologist who will be unaware of the study process.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient age between 18-50 years, physical status (ASA I) and candidate for elective surgery. Exclusion criteria: Patients with a history of asthma, chronic cough, respiratory infection in the past 4 weeks, Angiotensin converting enzyme inhibitor drugs, smoking, drug use, bronchodilator or steroid administration, Abnormal and extra sounds in the heart and lungs

Intervention groups
Intravenous injection of fentanyl will be given in three groups for 2, 15 and 30 seconds, respectively.The severity and incidence of cough will be recorded in a special form within 2 minutes after intravenous injection of fentanyl.

Main outcome variables
Incidence and severity of cough during anesthesia induction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200108046052N2**
Registration date: **2020-02-28, 1398/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-28, 1398/12/09**
Update count: **0**

Registration date
2020-02-28, 1398/12/09

Registrant information

Name
Motahareh Khojastehrad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3380 0885

Email address
motahareh.khojastehrad@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-19, 1398/11/30

Expected recruitment end date
2020-03-21, 1399/01/02

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of duration of injection time on the incidence and severity of fentanyl-induced cough (FIC)

Public title

The effect of fentanyl on cough

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient age between 18-50 years Physical Condition (ASA I) Candidate for elective surgery

Exclusion criteria:

Patients with a history of asthma Chronic cough Respiratory infection during the last 4 weeks Angiotensin converting enzyme inhibitor drugs Smoking Opioids users Use of bronchodilators or steroids Abnormal and excessive sounds in the heart and lungs

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a random number generating software, 150 random numbers were obtained. The numbers x≤50 fall into the first group, 50˂x≤100 in the second group, and 100˂x≤150 into the third group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of the duration of fentanyl injection. The information is recorded by an experienced anesthesiologist who was unaware of the study process and recorded in a special form.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bandar Abbas University of Medical Sciences

Street address

Shahid Mohammadi hospital, Republic Street

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2016-03-14, 1394/12/24

Ethics committee reference number

IR.HUMS.REC.1394.184

Health conditions studied

1

Description of health condition studied

Cough induced by injection of fentanyl in induction of anesthesia

ICD-10 code

A37.9

ICD-10 code description

Whooping cough, unspecified species

Primary outcomes

1

Description

Severity and incidence of fentanyl injection cough

Timepoint

Within 2 minutes after intravenous injection of fentanyl

Method of measurement

Classification form Incidence and severity of cough

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Fentanyl will be injected intravenously during 2 seconds. While receiving oxygen (6 l/min), all patients will receive Fentanyl (Fenijject 0.5 mg/10 ml, Aburaihan Co. in Iran) by an anesthesiologist at the dose of 2 µg/kg.

Category

Treatment - Drugs

2

Description

Intervention group 2: Fentanyl will be injected intravenously during 15 seconds. While receiving oxygen (6 l/min), all patients will receive Fentanyl (Feniject 0.5 mg/10 ml, Aburaihan Co. in Iran) by an anesthesiologist at the dose of 2 µg/kg.

Category

Treatment - Drugs

3

Description

Intervention group 3: Fentanyl will be injected intravenously during 30 seconds. While receiving oxygen (6 l/min), all patients will receive Fentanyl (Feniject 0.5 mg/10 ml, Aburaihan Co. in Iran) by an anesthesiologist at the dose of 2 µg/kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi hospital

Full name of responsible person

Hashem Jarineshin

Street address

Shahid Mohammadi hospital, Republic Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bandare-abbas 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

Full name of responsible person

Hashem Jarineshin

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Only the results section can be shared.
When the data will become available and for how long
Start access period 3 months after publishing results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Announced as a reference.
From where data/document is obtainable
motahareh.khojastehrad@gmail.com
What processes are involved for a request to access data/document
Send request by email
Comments