# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 Jun 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 (Feniject 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

**City**
Bandar Abbas

**Province**
Hormozgan

**Postal code**
7919915519

**Phone**
+98 76 3334 7002

**Email**
motahareh.khojastehrad@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Bandare-abbas University of Medical Sciences

**Full name of responsible person**
Hashem Jarineshin

**Street address**
Shahid Mohammadi hospital, Republic Street

**City**
Bandar Abbas

**Province**
Hormozgan

**Postal code**
7919915519

**Phone**
+98 76 3334 7003

**Email**
motahareh.khojastehrad@gmail.com

**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

**Street address**
Shahid Mohammadi hospital, Republic Street

**City**
Bandar Abbas

**Province**
Hormozgan

**Postal code**
7919915519

**Phone**
+98 76 3334 7001

**Email**
hjarineshin@yahoo.com

## Person responsible for scientific 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

**Street address**
Shahid Mohammadi hospital, Republic Street

**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7919915519
**Phone**
0987633347001
**Email**
hjarineshin@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Motahareh KHojasteh Rad
**Position**
Anesthesiologist
**Latest degree**
Master
**Other areas of specialty/work**
Physiology
**Street address**
Shahid Mohammadi hospital, Republic Street
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7919915519
**Phone**
+98 76 3334 7002
**Email**
motahareh.khojastehrad@gmail.com

## 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**