

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### Investigating the effect of morphine and fentanyl use in patients with new coronavirus (COVID-19)

#### Protocol summary

##### Study aim

Evaluation of changes in clinical symptoms and C-reactive protein in patients with COVID-19 following morphine and fentanyl use

##### Design

This clinical trial will be conducted with the participation of two parallel and random groups. Randomization was performed in that simple and individual method.

##### Settings and conduct

The present clinical trial will be performed at Masih Daneshvari Hospital in Tehran. For this purpose, 60 patients with the new coronavirus (COVID-19) will be included in the study. Patients are then randomly divided into two groups: morphine and fentanyl. Patients in the morphine group will receive 3 mg of morphine intravenously every 6 hours for 5 days, while in the fentanyl group, 1.5 mg/kg/h will receive 1.5 fentanyl for 2 hours a day for 5 days. They will receive consecutive.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Liver enzymes <2 times the normal range; sensitivity to drugs and alcohol • No intubation • Evidence of new coronavirus (COVID-19) (clinical or paraclinical) Exclusion criteria : sensitivity to opium; addiction to opium; addiction to alcohol

##### Intervention groups

Sixty patients with the new coronavirus (COVID-19) are being studied. Patients are then divided into morphine and fentanyl groups. Thus, we will have two intervention groups: 1- Patients in morphine group 2- Patients in fentanyl group

##### Main outcome variables

Respiratory and inflammatory indicators of patients are the main variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150725023332N4**

Registration date: **2021-03-08, 1399/12/18**

Registration timing: **retrospective**

Last update: **2021-03-08, 1399/12/18**

Update count: **0**

##### Registration date

2021-03-08, 1399/12/18

##### Registrant information

###### Name

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2283 1058

###### Email address

alirezajahangiri@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of morphine and fentanyl use in patients with new coronavirus (COVID-19)

##### Public title

The effect of morphine and fentanyl use in patients with corona

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Liver enzymes <2 times the normal range No intubation  
Evidence of new coronavirus (COVID-19) (clinical or  
paraclinical)

**Exclusion criteria:**

Sensitivity to opium Addiction to opium Addiction to  
alcohol

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

With simple randomization and using a random number table and individual randomization unit. To randomize, we use a table consisting of random digits 0 to 9. Each digit of this table is repeated the same on average. There is no pattern of recognizable numbers. In this method, each number is assigned to a treatment group. We start from the first line of the table and move down line by line. For the two treatments, we put the numbers 0 to 4 for treatment A and the numbers 5 to 9 for treatment B. The numbers in the first line of the table are as follows: 0,5,2,7,8,4,3,7,4,1,6,8,3,8,5,1,5,6,9,6, ... Now for people based on the above numbers, we have the following allocation: A, B, A, B, B,... We will continue the above process until the two groups are completed.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of  
Medical Sciences

**Street address**

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo  
Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Approval date**

2020-04-14, 1399/01/26

**Ethics committee reference number**

IR.SBMU.NRITLD.REC.1399.055

**Health conditions studied****1****Description of health condition studied**

SARS-COV-2

**ICD-10 code**

B34.2

**ICD-10 code description**

Coronavirus infection, unspecified

**Primary outcomes****1****Description**

C-Reactive Protein (CRP)

**Timepoint**

Before applying the intervention, then 24 hours and 48  
hours after the intervention

**Method of measurement**

Biochemical tests (spectrophotometric method)

**2****Description**

Immunoglobulin G (IgG)

**Timepoint**

Before applying the intervention, then 24 hours and 48  
hours after the intervention

**Method of measurement**

Immunological tests (competitive ELISA method)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First intervention group: Morphine group (20 patients): 3  
mg of morphine (Product of Faran Shimi Pharmaceutical  
Company) is given intravenously every 6 hours for 5  
days.

**Category**

Treatment - Drugs

**2****Description**

Second intervention group: Fentanyl Group (20 people):  
1.5 mcg/kg/h fentanyl (Product of Faran Shimi  
Pharmaceutical Company) is given for 2 hours a day for 5  
consecutive days

**Category**

Treatment - Drugs

**3**

**Description**

Control group: In the control group, placebo capsules  
(Product of Faran Shimi Pharmaceutical Company) were  
used exactly at the above intervals

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Masih Daneshvari hospital

**Full name of responsible person**

Alireza Jahangirifard

**Street address**

Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2610 5050

**Email**

alirezajahangiri@sbmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo  
Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 23871

**Email**

zarghi@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Jahangirifard

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2610 5050

**Email**

alirezajahangiri@sbmu.ac.ir

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Vahid Salimi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Virology

**Street address**

Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1956944413  
**Phone**  
+98 21 2610 5050  
**Email**  
vahidsalimii@gmail.com

Tehran  
**Province**  
Tehran  
**Postal code**  
1956944413  
**Phone**  
+98 21 2610 5050  
**Email**  
b.mirtajani@theaasm.org

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Seyed Bashir Mirtajani  
**Position**  
Research Director  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Genetics  
**Street address**  
Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout  
**City**

## 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

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

### Statistical Analysis Plan

Not applicable

### 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

Not applicable

### Data Dictionary

Not applicable