

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

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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
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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

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**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

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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
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Masih Daneshvari Hospital, Darabad Avenue, Shahid
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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