Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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

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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

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
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Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
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Other areas of specialty/work
Medical Genetics
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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