

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of new trial drug on improving of clinical and paraclinical symptoms in patients ICU with COVID-19

Protocol summary

Study aim

Evaluation the effect of one new trial drug on the clinical and paraclinical symptoms in hospitalized patients with COVID-19

Design

A randomized controlled, double blind clinical trial with a parallel-group design; consisted of 120 patients, in which participants will be randomly allocated into trial groups using www.randomization.com

Settings and conduct

This study is a randomized controlled two blinded trial that will be conducted on COVID-19 patients who referred to Ali Asghar Hospital of Shiraz in two groups (intervention and control groups). The patients, researcher, monitoring committee, and statistical analyst will be blind to the received active drug or placebo. Participants will be allocated into trial groups randomly using randomization site. Patients will receive a drops containers of new trial drug or placebo by giving 6 sublingual drops every 3hours for 14days. Random allocation sequences will be generated by the non-involved person in the research. Both groups will receive routine treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 15 years and older with COVID-19 who had hospitalized; Having a definite disease; Having a signed informed consent form to participate in the study; Non-inclusion: not participation in another clinical trial simultaneously.

Intervention groups

In the intervention group, participants will receive six drops containing 433 ± 5 mg sublingual new trial drug every 3 hours for 14 days. The control group will receive a placebo, resembled herbal medicine with the same prescription. Both groups will receive routine treatments.

Main outcome variables

Respiratory Rate (RR); Oxygen saturation (SpO₂); Serum white blood cell count; serum CRP level; ESR; the number of hospitalization days; Mortality

General information

Reason for update

Change the scientific title of the experiment

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047373N2**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **prospective**

Last update: **2021-10-13, 1400/07/21**

Update count: **3**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Ahmad Hosseinpour

Name of organization / entity

Health Medicine Chemistry Company

Country

Iran (Islamic Republic of)

Phone

+98 71 3739 1910

Email address

ahosseinpour3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-14, 1400/01/25

Expected recruitment end date

2022-06-02, 1401/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of new trial drug on improving of clinical and paraclinical symptoms in patients ICU with COVID-19

Public title

Effect of new trial drug on clinical and paraclinical symptoms in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having definite COVID-19 disease and get hospitalized
Both sexes
Age over 15 years
Obtaining informed consent to participate in the trial
Non-participation in another clinical trial simultaneously
Patients admitted to ICU

Exclusion criteria:

Diagnosis of the disease just based on physician diagnosis
Pregnancy (according to the patient's statement and examination by a physician)
Breastfeeding (according to the patient's statement)

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to trial groups (intervention and placebo groups) randomly through site www.randomization.com block sizes of 4 with an allocation ratio of 1:1. Patients will receive a new trial drug sublingual 433 ± 5 mg or placebo . 6 sublingual drops will be taken every 3hour for 14days . Random sequencing allocation will be produced by the person who has not to participate in the research. drops will be numbered from 1 to 120 according to the sequence generated. Both groups will receive routine treatments.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a randomized controlled two-blind clinical trial. This means that patient, researcher, safety and data monitoring committee, clinical caregiver and statistical analyst will be blind to the received medication. Each person will be given a new trial drug or placebo in the identical shape and weight.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice chancellor for research affairs, seventh floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸-۱۴۳۳۶

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.SUMS.REC.1399.1367

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Respiratory Rate

Timepoint

Daily

Method of measurement

Observation

2

Description

Oxygen saturation (SpO2)

Timepoint

Daily

Method of measurement

Pulse Oximeter

3

Description

Serum White Blood Cell count

Timepoint

Before intervention and 14 days after intervention

Method of measurement

Laboratory cell counter

4

Description

Serum CRP level

Timepoint

Before intervention and 14 days after intervention

Method of measurement

Biochemical method

5

Description

ESR (Erythrocyte Sedimentation Rate)

Timepoint

Before intervention and 14 days after intervention

Method of measurement

Checking the sedimentation rate of erythrocytes in a special tube within one hour

6

Description

Number of hospitalization days

Timepoint

After intervention

Method of measurement

Questionnaire

7

Description

Mortality

Timepoint

Daily

Method of measurement

Questionnaire

Secondary outcomes

1

Description

The end time of dry Cough

Timepoint

Daily

Method of measurement

Daily symptom recording questionnaire

2

Description

The time of recovery from difficulty in breathing or shortness of breath

Timepoint

Daily

Method of measurement

Daily symptom recording questionnaire

3

Description

The time of recovery of temperature equal to or grater than 37.8 C

Timepoint

Daily

Method of measurement

Daily symptom recording questionnaire

Intervention groups

1

Description

In the intervention group, participants will receive new trial drug 6 drops every 3hours for 14 days. The control group will receive a placebo (no therapeutic value), resembled the herbal medicine with the same prescription. Both groups will receive routine treatments.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive a placebo, resembled the new trial drug with the same prescription. Both groups will receive routine treatments.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shiraz Medical Sciences Hospitals

Full name of responsible person

Hossain Faramarzi

Street address

Imam Hossein square; Zand street

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3230 5884

Email

hossainfaramarzi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Health Medicine Chemistry Company

Full name of responsible person

Ahmad Hosseinpour

Street address

No. 256, alley 7, Solh boulevard, Maharat square

City

Shiraz

Province

Fars

Postal code

7177654547

Phone

+98 71 3739 7910

Email

ahosseinpour3@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Health Medicine Chemistry Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Health Medicine Chemistry Company

Full name of responsible person

Ahmad Hosseinpour

Position

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Latest degree

Master

Other areas of specialty/work

Medical Nanotechnology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ahmad Hosseinpour

Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Title and more details about the data/document

All participants' data can be shared after it becomes unrecognizable

When the data will become available and for how long

End of october

To whom data/document is available

healthcare professional- academic members of universities

Under which criteria data/document could be used

An official request from the organization

From where data/document is obtainable

Shiraz University of Medical Sciences

What processes are involved for a request to access data/document

In case of requesting data for the study, the applicant must first introduce himself or herself and the relevant organization to determine the purpose of the data request and state for what purpose this data is used. After submitting the request, if the researchers of this study prove that the data of this study can advance the therapeutic goals, the information will be sent as long as the data remains confidential. This process takes two weeks.

Comments