Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 trough 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
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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
.
Latest degree
Master
Other areas of specialty/work
Medical Nanotechnology
Street address
No. 256, alley 7, Solh boulevard, Maharat square
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
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Other areas of specialty/work
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City
Shiraz
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7177654547
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Email
ahosseinpour3@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

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- ācademic 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