Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trials of a syrup from three medicinal plants with effective index glycyrrhizin index in reducing inflammation, cough, and duration of hospitalization caused by Covid-19

Protocol summary

Study aim

study on the effects of Hero Syrup on the outcome and death of COVID-19 infection of human

Design

Patients would be randomly divided into 2 arm parallel groups by Stratified allocation method and treated in a triple-blind clinical trial. The patients would be subgrouped into 8 laid depending on the severity of infection, sex, and age (over 45 years old and below). For each subgroup, there would be random permuted blocks. There would be 41 patients in each group. After the first phase of the trial, if the result were satisfactory, the trial would proceed into the 2nd phase and the drug would be tested on 100 patients.

Settings and conduct

This trial would be a triple-blinded clinical examination of the Hero Syrup on COVID-19 patients of Yasudj City of Iran. The Syrup would be prepared in Khrramabd Medical and Pharmacology Schools labeled and will be sent for a clinical trial in the Imam Sadjad Hospital of Yasudj city. The Doctors, patients, and data analyzers all would be blinded for the drug or placebo in both sites.

Participants/Inclusion and exclusion criteria

patients aged between18 to 65 who have proven to be infected with SARS Cov2 and have the ability to consume the drug and answer the questions in the interview are eligible for participation in the study. Patients who are hospitalized in the ICU ward, pregnant or has hypersensitivity to the drug will not accepted to this study.

Intervention groups

patients would be randomly divided into 2 groups (Stratifi8ed random allocation) The test groups also would be divided into 8 layers depending on the severity of infection, sex, and age groups. The control group also would be equally divided.

Main outcome variables

The triple-blinded clinical trial would assess the in the following rates : death, need for hospitalization, need for ICU room, need for ventilation of the patient, cough, and time to recovery from the COVID-19 infection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220830055834N1**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**
Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

Gholam Reza Talei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

taleireza@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-03, 1401/09/12

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials of a syrup from three medicinal plants with effective index glycyrrhizin index in reducing inflammation, cough, and duration of hospitalization caused by Covid-19

Public title

Clinical trial for a herbal syrup (named Hero) in reduction of COVID 19 respiratory infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 65 years old Proven infection with COVID - 19 Ability (mental and physical) to use the drug syrup Lack of hypersensitivity to the drug and similar compounds. Ability to respond to contact and interview about the effectiveness of the drug. patient must have not be hospitalized in the ICU ward.

Exclusion criteria:

Negative criteria for COVID-19 infection

Age

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

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Drug or placebo would be prepared in Khorramabad City and after labelling with a code number and A or B group would be recorded by Secretary of Research of the Lorestan University of(LUMS) and the code would be stored in his safe in his office. The bottles of drugs and placebo are all would be similar in all aspects except number of labels. The bottles then would be send to Yasuj City for Clinical trials. Assignment of recipient of drugs or placebo would be based on Stratified Random Allocation method. This would be based on severity of infection(mild or moderate) , age and sex(8 groups). In each group there would be random permuted block method for allocation of participants. At the end the data would be analyzed in 2 groups (A and B) by the Biostatistician and the decoder would open the labels for conclusion of the results.

Placebo

Used

Assignment

Parallel

Other design features

Two groups are different by the severity of infection

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Lorestan University of Medical Sciences

Street address

Kamalvand

City

Khorramabad

Province

Lorestan

Postal code

6815144311

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.LUMS.REC.1399.313

Health conditions studied

1

Description of health condition studied

Respiratory Infection of COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19: confirmed by laboratory testing

Primary outcomes

1

Description

pressure of Oxygen in the blood

Timepoint

At the admission time and every hour for the first 12 hours, depending on the severity of symptoms every 1 hour. then twice a day up to the end of the trial

Method of measurement

Oxymeter for blood oxygen

2

Description

shortness of breath

Timepoint
At the admission time and every hour for the first 12 hours, depending on the severity of symptoms every 1 hour. then twice a day up to the end of the trial
Method of measurement
observation for shortage of breath

3

Description
fever
Timepoint
At the admission time and every hour for the first 12 hours, depending on the severity of symptoms every 1 hour. then twice a day up to the end of the trial
Method of measurement
Thermometer for fever

4

Description
cough
Timepoint
At the admission time and every hour for the first 12 hours, depending on the severity of symptoms every 1 hour. then twice a day up to the end of the trial
Method of measurement
observation of cough

Secondary outcomes

1

Description
The death rate would be compared in 2 groups of test and control. In the test group, they received Hero Syrup and routine treatment, and in the control group, they received only routine treatment.
Timepoint
At the end of 14 days of infection period
Method of measurement
Counting the death of patients in 2 groups according to the hospital report and comparing it.

2

Description
Counting the patients who were hospitalized in the ICU and the duration of their hospitalization in that ward.
Timepoint
from the beginning of the symptoms for 14 days, if the patient needed ICU, the duration of hospitalization in the ward would be recorded according to the hospital record.
Method of measurement
Counting the days of hospitalization in the ICU ward according to the hospital record.

3

Description
patients who needed Ventilators during the 14 days of clinical COVID-19 infection would be followed, counted, and compared.
Timepoint
At the end of 14 days of COVID-19 infection, those patients who needed Ventilators would be followed counted, and compared.
Method of measurement
Patients who needed the use of Ventilation would be counted and compared in these 2 groups

4

Description
Day(s) of hospitalization in ICU ward, if necessary, would bge compared in two groups
Timepoint
from the beginning of the symptoms for 14 days, if the patient needed ICU, the duration of hospitalization in the ward would be recorded according to the hospital record and compared in the 2 groups
Method of measurement
Counting the days of hospitalization in the ICU ward according to the hospital record and would be compared

5

Description
patients who needed a Ventilator during the 14 days of clinical COVID 19 infection would be followed and days of this requirement would be compared in two groups.
Timepoint
At the end of 14 days of COVID-19 infection
Method of measurement
At the end of 14 days of COVID-19 infection, days of used Ventilators by patients would be counted and compared.

Intervention groups

1

Description
Control group: The routine treatment would be given to this group as well as Placebo which would look and taste like the Hero Syrup.
Category
Treatment - Drugs

2

Description
Intervention group: There would be a routine treatment for this group as well as the Hero Syrup which would be given according to the protocol for 7 days (3 times a day with 350 milligrams/mili liter)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sadjad Hospital of Yasudj City

Full name of responsible person
Dr. Gholam Abbas Sabz
Street address
Pezeshk Street
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Yasudj City
Province
Kohgilouyeh-va-Boyrahmad
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emamsajad@yums.ac.ir
Web page address
https://research.yums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Professor Bahram Rasulian
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Lorestan University of Medical Sciences, Kamalvand, Pardis, Khorramabad, Lorestan, Iran.
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Email
researchlums@lums.ac.ir
Web page address
http://research.lums.ac.ir/
Grant name
1805003000 Research for practical use
Grant code / Reference number
شماره برنامه1805003000
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical Sciences
Proportion provided by this source
60
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

2

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr Abbas Sabz
Street address
Pezeshk Street
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yasudj
Province
Kohgilouyeh-va-Boyrahmad
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+98 74 3322 0168
Email
emamsajad@yums.ac.ir
Web page address
https://research.yums.ac.ir/
Grant name
Resarch for application use number 124010
Grant code / Reference number
پژوهش های علمی کاربردی به شماره دستگاه اجرایی 124410
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj University of Medical Sciences
Proportion provided by this source
40
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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Gholam Reza Talei
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Virology
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Full name of responsible person
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Position
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http://en.lums.ac.ir/index.php?module=fdk&func=loadmodule&system=fdk&sismodule=management/content_view.php&sisOp=view&ctp_id=58&cnt_id=78093&id=189

Person responsible for updating data

Contact

Name of organization / entity
Ghohar Shafa Medical device manfactory

Full name of responsible person
Somaieh Sabzali

Position
Quality Control manager

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of patients

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available