Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of Gallecina® oral capsules, a hydrogen sulfide prodrug, as an adjuvant therapy in hospitalized patients with COVID-19: a randomized placebo-controlled triple-blind clinical trial

Protocol summary

Study aim
Evaluation of the efficacy of Gallecina® oral capsules, a hydrogen sulfide prodrug, as an adjuvant therapy in hospitalized patients with COVID-19

Design
a randomized placebo-controlled triple-blind phase 3 clinical trial on 148 patients with COVID-19

Settings and conduct
In the drug and placebo group, the capsules will be prescribed for a final period of 6 days. During treatment, SaO2 status will be monitored continuously once a day, and CT scan of the lung and CRP and CBC diff will be recorded at the beginning and end of the study. The patient's clinical signs and vital signs will be evaluated daily.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Hospitalized patients aged 18 to 65 years with definite diagnosis of SARS-CoV-2 infection based on PCR or detection of pulmonary involvement on CT scan. Exclusion criteria: History of garlic allergy and garlic-derived products Pregnancy and lactation period Low patient pressure at the beginning of the study (below 120/80) Malignancy, Immune deficiency, Alzheimer's, Multiple organ failure, Encephalopathy

Intervention groups
Consumption of Gallecina® capsules every 8 hours for 6 days

Main outcome variables
Time to improve clinical condition, time to normalize clinical symptoms, number of patients with change in oxygenation status, improved lung CT scan, change in quantitative CRP, number of deaths.

General information

Reason for update
Increasing the number of the disease centers and predicted sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT20201111049347N1**
Registration date: **2021-04-16, 1400/01/27**
Registration timing: **prospective**

Last update: **2021-04-27, 1400/02/07**
Update count: **2**

Registration date
2021-04-16, 1400/01/27

Registrant information

Name
Sina Rezaei

Name of organization / entity
Samisaz pharmaceutical company

Country
Iran (Islamic Republic of)

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+98 51 3541 3385

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sina-rezaei@samisaz.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of Gallecina® oral capsules, a hydrogen sulfide prodrug, as an adjuvant therapy in hospitalized patients with COVID-19: a randomized placebo-controlled triple-blind clinical trial

Public title
Effectiveness of enriched garlic extract in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hospitalized patients with definite diagnosis of SARS-CoV-2 infection based on PCR or detection of pulmonary involvement on CT scan. Hospitalized patients aged 18 to 65 years old

Exclusion criteria:
History of garlic allergy and garlic-derived products Pregnancy and lactation period Low patient pressure at the beginning of the study (below 120/80) Malignancy, Immune deficiency, Alzheimer's, Multiple organ failure, Encephalopathy

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

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **248**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of patients in two groups of drugs and placebo is done by preparing a randomization list from randomization.com using Permuted Blocked Randomization method. In this method, blocks of ten are used for two treatments A (drug) and B (placebo). Due to the possible loss of samples during the study, the number of patients is estimated to be 30% more than the calculated sample size and is placed in the software. The number of blocks is obtained by dividing the estimated sample size by ten. The output file shows the assignment of drug or placebo treatment to patient number 1 to the last patient sample size.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The medicine and placebo are prepared with the same appearance and in the same package with the relevant code. For patients who meet the inclusion criteria, Gallecina® is prescribed. The study package is provided to the nurse in the ward. However, neither the nurse nor the researcher is aware of the contents of the package when receiving the medication. After recording the data, the results are provided in the form of code to the person who performs the data analysis. Analysis is performed based on the provided codes. Decrypting the codes is done after analysis by a person who knows how to place patients in control and intervention groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of North Khorasan University of Medical Sciences

Street address
North Khorasan University of Medical Sciences, Dowlat Blvd, bojnurd, 9414975516, Iran

City
Bojnord

Province
North Khorasan

Postal code
9414975516

Approval date
2021-01-11, 1399/10/22

Ethics committee reference number
IR.NKUMS.REC.1399.127

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
The time to recovery, defined as the from the time of randomization and start of treatment to the first day of recovery: not hospitalized, hospitalized with not requiring supplemental oxygen and/or no longer requiring ongoing medical care (used if hospitalization was extended for infection-control reasons).

Timepoint
From the time of randomization

Method of measurement
Number of days

2

Description
Time to normalize fever (in hours): From the time of randomization and start of treatment, to be normalized fever. The criteria for normalization is: Fever - ≤36.9°C or -axilla, ≤37.2 °C oral.
Timepoint
every 6 hour
Method of measurement
Body temperature

3

Description
Time to improve shortness of breath (in hours): From the time of randomization and start of treatment, to be normalized respiratory rate. The criteria for normalization is: Respiratory rate - ≤24/minute on room air.
Timepoint
every 6 hour
Method of measurement
Respiratory rate

4

Description
Time to normalize oxygen saturation (in hours): From the time of randomization and start of treatment, to be normalized oxygen saturation. The criteria for normalization is: Oxygen saturation - >94% on room air.
Timepoint
every 6 hour
Method of measurement
O2 saturation measurement

5

Description
Time to improve cough (in hours): From the time of randomization and start of treatment, to be improved cough. The criteria for normalization is: Cough - mild or absent on a patient-reported scale of severe, moderate, mild, absent.
Timepoint
every 6 hour
Method of measurement
Cough rate

6

Description
Number of patients with changes in oxygen delivery status. The categories are as follows: 1. hospitalized, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalization was extended for infection-control reasons); 2. hospitalized, not requiring supplemental oxygen but requiring ongoing medical care (Covid-19–related or other medical conditions); 3. hospitalized, requiring any supplemental oxygen; 4. hospitalized, requiring noninvasive ventilation or use of high-flow oxygen devices; 5, hospitalized, receiving invasive mechanical ventilation.
Timepoint
End of the study
Method of measurement
Number of days

7

Description
Improved lung CT scan
Timepoint
Before the intervention and the end of the study
Method of measurement
CT Scan

8

Description
Change in measured quantitative CRP
Timepoint
Before the intervention and the end of the study
Method of measurement
blood test

9

Description
Mortality rate
Timepoint
End of the study
Method of measurement
Number of patients who died

Secondary outcomes

1

Description
Incidence of adverse effects: Acute respiratory failure, hypotension, viral pneumonia, acute renal failure, anemia, decreased hemoglobin, decreased GFR, increased creatinine, hyper or hypoglycemia, increased LFT.
Timepoint
End of the study
Method of measurement
Incidence of the adverse effect

Intervention groups

1

Description
Intervention group: Based on the patient's clinical status, and treatment criteria, the following antiviral and anti-inflammatory drugs may be prescribed to the patient: Interferon beta-1a with a dose of 44 micrograms by subcutaneous injection every other day in the amount of 5 to 7 doses of Favipiravir with a dose: the first day of 1800 mg every 12 hours and from the following days 800

mg every 12 hours for 10 days up to a maximum of 14 days. Persistent oxygen demand despite supportive therapy and SpO2 between 90-93%, corticosteroids can be given in low doses: Dexamethasone 8 mg intravenously daily for up to 10 days. Or oral prednisolone tablets 0.5mg / kg for a maximum of 10 days. Remdesivir IV: 200 mg as a single dose on day 1, followed by 100 mg once daily. Total duration is 5 days. To the above drug treatment, one Gallecina® capsule (containing processed garlic extract) prepared by Sami Saz Pharmaceutical Company is added every 8 hours for 6 days.

Category

Treatment - Drugs

2

Description

Control group: Based on the patient's clinical status, and treatment criteria, the following antiviral and anti-inflammatory drugs may be prescribed to the patient: Interferon beta-1a with a dose of 44 micrograms by subcutaneous injection every other day in the amount of 5 to 7 doses of Favipiravir with a dose: the first day of 1800 mg every 12 hours and from the following days 800 mg every 12 hours for 10 days up to a maximum of 14 days. Persistent oxygen demand despite supportive therapy and SpO2 between 90-93%, corticosteroids can be given in low doses: Dexamethasone 8 mg intravenously daily for up to 10 days. Or oral prednisolone tablets 0.5mg / kg for a maximum of 10 days. Remdesivir IV: 200 mg as a single dose on day 1, followed by 100 mg once daily. Total duration is 5 days. To the above drug treatment, one placebo capsule (has all the specifications of Gallecina® drug but does not have the active ingredient Gallecina®) prepared by Sami Saz Pharmaceutical Company is added every 8 hours for 6 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital of Mashhad

Full name of responsible person
Dr. Saeed Hafizi Lotfabadi

Street address
Khorasan Razavi - Mashhad city - Torqabeh Shandiz intersection - Zafaranieh Boulevard - Dr. Ali Shariati Hospital

City
Mashhad

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2

Recruitment center

Name of recruitment center
Emam Hasan Hospital

Full name of responsible person
Dr. Mohammad Bagher Oghazian

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Arkan road

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3

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Dr. Mehrdad Dargahi

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4

Recruitment center

Name of recruitment center
Hagi Arbabi Selected center of covid19

Full name of responsible person
Dr. Mohamdreza Salehi

Street address
Shahid Salimi 4th Avenue, Toos 74th Ave, Toos Blvd, Mashhad town

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Province
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Sinarezaei@yaho.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Samisaz Pharmaceutical company
Full name of responsible person
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461,No. 9,North Talash Boulevard,Toos Industrial City,Mashhad,Iran
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Email
info@samisaz.com
Web page address
http://samisaz.com/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Samisaz Pharmaceutical 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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Samisaz Pharmaceutical Co.
Full name of responsible person
Dr. Sina Rezaei
Position
Production Manager
Latest degree
Medical doctor
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All details of the study will be published in the form of a scientific article
When the data will become available and for how long
6 months after the end of the study
To whom data/document is available
All interested
Under which criteria data/document could be used
Preserving the intellectual rights of publishers in order to promote the study
From where data/document is obtainable
Refer to the general accountability officer of the trial
What processes are involved for a request to access data/document
6 months after the end of the study and after the publication of the article via the following email : sina-rezaei@samisaz.com
Comments