Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness and safety of Gallecina(R) capsule on the clinical symptoms of outpatients with COVID-19

Protocol summary

Study aim

Determining the effectiveness and safety of Gallecina(R) capsule in the treatment of outpatients Covid 19 and also evaluating its effects on reducing mortality or hospitalization due to (SARS-CoV-2)

Design

This is a double-blind clinical study of phases 2-3. This study will be performed on 140 patients who are divided into two groups. Randomly, a group of outpatients with Covid-19 were given a 90 mg capsule of Gallecina (R) (made by SamiSaz Co.) three times a day and a group of placebo capsules for 10 days with common medications. The blocking method and randomization site "Randomization.com" are used for randomization. Patients are followed up during this period in terms of clinical symptoms and severity of the disease and the need for hospitalization.

Settings and conduct

This study is performed in 16-h clinics of Covid-19 in Mashhad. Physician, patient, and data analyst are unaware of the medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Outpatients with COVID-19; Confirming RT-PCR test for SARS-CoV-2; Blood oxygen saturation more than 90%; Age 18-60 years Exclusion criteria: Pregnant women; Breastfeeding women

Intervention groups

Placebo group: receiving common treatments + placebo of Gallecina (R) capsule (made by SamiSaz Co.) three times a day / Intervention group: receiving common treatments + 90 mg capsule of Gallecina (R) (made by SamiSaz Co.) three times a day

Main outcome variables

he rate of recovery time from the time of randomization of patients to the improvement of clinical symptoms including fever, cough and myalgia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038199N12**
Registration date: **2022-02-21, 1400/12/02**
Registration timing: **prospective**

Last update: **2022-02-21, 1400/12/02**
Update count: **0**

Registration date

2022-02-21, 1400/12/02

Registrant information

Name

Vahid Reza Askari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2264

Email address

askariv941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness and safety of Gallecina(R) capsule on the clinical symptoms of outpatients with COVID-19

Public title
Gallecina(R) capsule in COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Outpatients with COVID-19 Confirmed with RT-PCR SPO2 more than 90% Age between 18 to 60 years old
Exclusion criteria:
Pregnant women Breastfeeding women
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
The volume of each block will be 4. Then write a list of blocks and assign numbers to them, for example (AABB (1) - BBAA (2) - BABA (3) - BAAB (4)) which according to the sample size of 140 people, we have 35 blocks. Then, random numbers between one and 35 are selected according to the Randomization.com randomization site, and finally, the treatment allocation list is determined based on random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the use of a placebo similar to interventional therapy, the physician associated with the participants and participants will not be informed of the assigned treatment and also the analyst will be unaware of the treatment assigned to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals codes A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences
Street address
Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2021-11-09, 1400/08/18
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.550

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Time to recover from illness based on questionnaire
Timepoint
Before intervention and 3, 7 and 10 days after beginning the intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: receiving common treatments, including adult cold two tablets every eight hours, one tablespoon of diphenhydramine syrup every 8 hours, vitamin C 1000 mg effervescent + placebo of Gallecina (R) capsule (made by SamiSaz Co.) three times a day
Category
Placebo

2

Description
Intervention group: Intervention group: receiving common treatments, including adult cold two tablets every eight hours, one tablespoon of diphenhydramine syrup every 8 hours, vitamin C 1000 mg effervescent + 90 mg capsule of Gallecina (R) (made by SamiSaz Co.) three times a day

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person
Dr Vahid Reza Askari

Street address
Mashhad University of Medical Science, Azadi Square

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9177948564

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askariv@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Majid Ghaiour Mobarhan

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Deputy of Research and Technology of the University , Qurashi Building, Next to Hoveyzeh Cinema, University Street

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Mashhad University of Medical Sciences

Full name of responsible person
Vahid Reza Askari

Position
Assistant professor of clinical pharmacology

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Faculty of medicine, Paradise of University, Vakil-Abad Blvd., Azadi Sq., Mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Vahid Reza Askari

Position
Assistant professor of clinical pharmacology

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Person responsible for updating data

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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
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
Undecided - It is not yet known if there will be a plan to make this available