Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of Ginger on clinical manifestations and paraclinical features of patients with COVID-19: A randomized double-blind placebo-control clinical trial

Protocol summary

Study aim

Evaluation of the effects of Ginger on clinical symptoms and laboratory signs in patients with COVID-19

Design

A phase 3, Placebo-controlled, Paralleled, double-blind, randomized clinical trial, 84 patients, randomized using blocks

Settings and conduct

This study will be conducted at the Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas.The study population is 84 patients with COVID-19 (42 patients in control group and 42 in study group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with positive polymerase chain reaction (PCR) test for COVID-19 or/and lung involvement in imaging, age ≥18 years, primary clinical symptoms, non-hospitalized mild, and signing informed consent. Exclusion Criteria: Patients with underlying diseases, includingchronic hepatitis, cirrhosis, cholestatic liver diseases, cholecystitis, and peptic ulcers, use of anticoagulant drugs like warfarin, and hormonal drugs, history of allergy to ginger, and pregnancy and breastfeeding

Intervention groups

Group A will be patients receiving standard treatment of COVID-19 according to the Ministry of Health's protocol. Group B will be patients receiving, in addition to the standard treatment, a ginger-based herbal tablet, at a dose of 1000 mg three times a day for a period of seven days.

Main outcome variables

Checking the SARS-CoV-2 clearance, improvement of fever Evaluation of white blood cell count Requremet for hospital admission Occurrence of adverse drug reactions

General information

Reason for update

Moderate patients take many antivirals and other drugs that might interact with Ginger preparations. Moreover, the process of patient recruitment was very slow considering eligibility criteria. Hence, the protocol of the trial updated in eligibility criteria, intervention, and outcomes for outpatients with Covid-19. This trial was also conducted on outpatients (mild) with COVID-19, instead of inpatients (moderate).

Acronym

IRCT registration information

IRCT registration number: **IRCT20200506047323N1**
Registration date: **2020-05-23, 1399/03/03**
Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**
Update count: **1**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name
Mohammad Fathalipour
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date
2021-02-19, 1399/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of Ginger on clinical manifestations and paraclinical features of patients with COVID-19: A randomized double-blind placebo-control clinical trial

Public title
The effects of Ginger in treatment COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥18 years Positive polymerase chain reaction (PCR) test for COVID-19 or/and lung involvement in imaging Primary clinical symptoms Hospitalized Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm
Exclusion criteria:
Underlying diseases, including chronic hepatitis, cirrhosis, cholestatic liver diseases, cholecystitis, and peptic ulcers Use of anticoagulant drugs like warfarin, and hormonal drugs History of allergy to ginger Pregnancy and breastfeeding
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data and Safety Monitoring Board

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be performed (each block consists 6 patients). Allocation sequence and concealment codes will be generated using www.sealedenvelope.com. The closed envelope method will be used to hide the allocation sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
The medication and placebo will be coded by the project manager. Patients will be randomly allocated within the blocks based on the hidden codes, and study participants, physicians, and nurses who evaluate the outcomes will be blind to the intervention and studied groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Jomhuri Eslami Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Approval date
2020-05-20, 1399/02/31
Ethics committee reference number
IR.HUMS.REC.1399.130

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
U07.2
ICD-10 code description
COVID-19, virus not identified

Primary outcomes

1

Description
SARS-CoV-2 clearance
Timepoint
Before intervention and day 7
Method of measurement
PCR test

2

Description
fever
Timepoint
Before intervention and daily during the study
Method of measurement
Thermometer

3

Description
White blood cell count
Timepoint
Before intervention and day 7
Method of measurement
Labratory

Secondary outcomes

1

Description
Hospital admission
Timepoint
During the intervention
Method of measurement
Questionnaire

2

Description
Incidence of serious adverse events
Timepoint
Before intervention and daily during the study
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: The standard treatment regimen for COVID-19 along with a Ginger-based herbal medicine (Vomigone 500 mg tablets, registration number: 9406633051781240, Dineh Iran Pharmaceutical Company) at a dose of 1000 mg three times a day for a period of seven days
Category
Treatment - Drugs

2

Description
Control group: The standard treatment for COVID-19 based on the Ministry of Health's protocol including hydroxychloroquine sulfate (Amin Pharmaceutical company, Isfahan) at a dose of 200 mg twice a day for a period of seven days, along with a Vomigone-liked placebo tablets (Dineh Iran Pharmaceutical Company) at a dose of two tablets three times a day for a period of seven days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Parivash Davoodian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hormozgan University of Medical Sciences
Proportion provided by this source
100
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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mohammad Fathalipour
Position
Consultant
Latest degree
Ph.D.
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Medical Pharmacy
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Person responsible for scientific inquiries

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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
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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information regarding the study outcomes will be shared.
When the data will become available and for how long
Data will become available after publication of obtained results
To whom data/document is available
Only academic institutions
Under which criteria data/document could be used
The study protocol or proposal should be approved by Ethics committee of institutions. The rights of authors and sponsors should be respected.

From where data/document is obtainable

M.fathalipour@yahoo.com M.fathalipour@hums.ac.ir

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

Requests should be addressed to the Technology and Research Vice-chancellery of Hormozgan University of Medical Sciences and the project executor should informed.

Comments