

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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, 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, 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 Requirement 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

Country

Iran (Islamic Republic of)

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+98 76 3371 0406

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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

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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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Associate professor

Latest degree

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Other areas of specialty/work

Infectious diseases

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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 be informed.

Comments