

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of feneel_terminalia chebula (FT®) powder on clinical and paraclinical symptoms in patients with Covid 19.

Protocol summary

Study aim

Reduction of hospitalization period and failure to enter the critical phase and mortality.

Design

A clinical trial with a control group with a randomized parallel group.

Settings and conduct

In Amir Al-Momenin Hospital in Qom in two groups of intervention and control as follows: Intervention group: FT® powder recipient along with the protocol of the Ministry of Health. Control group: receive only the treatment protocol of the Ministry of Health.

Participants/Inclusion and exclusion criteria

Major entry conditions: 1. Inpatients diagnosed with Covid 19. 2. Patients with Covid 19 who wish to participate in the study. 3. No serious heart disease, liver, kidney, blood pressure above 160 mm Hg. 4. Patients who do not receive insulin. 5. Non-pregnancy in women. 6. A maximum of 48 hours have passed since the beginning of the patient's hospitalization. Major conditions of non-entry: 1. Dissatisfaction with continuing treatment 2. Need to receive medical services in the intensive care unit.

Intervention groups

1. Intervention Description: Intervention group: Ministry of Health treatment protocol + FT® powder Category: Therapy - Drugs 2. Intervention description: Control group: Treatment protocol of the Ministry of Health Classification: Control

Main outcome variables

1. Hospitalization days 2. Clinical and vital signs 3. Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150819023685N3**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

Registration date

2021-08-16, 1400/05/25

Registrant information

Name

Samira Khani

Name of organization / entity

Qom University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 25 3783 2370

Email address

skhani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of feneel_terminalia chebula (FT®) powder on clinical and paraclinical symptoms in patients with Covid 19.

Public title

Evaluation of the effectiveness of black halilah and fennel powder in clinical symptoms of patients with coronavirus.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inpatients diagnosed with Covid 19. Patients with Covid 19 who wish to participate in the study No serious heart disease, liver, kidney, blood pressure above 160 mm Hg Patients who do not receive insulin Non-pregnancy in women. A maximum of 72 hours have passed since the beginning of the patient's hospitalization.

Exclusion criteria:

1. Dissatisfaction with continuing treatment. 2. Need to receive medical services in the intensive care unit.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the site <https://www.sealedenvelope.com> In the random list section, by entering the grouping A, B and the number of samples 70, as well as the volume of 2,4,8 blocks, we get a random list. I consider one group as the intervention group and the other as the control group. Patients who meet the inclusion criteria are included in one of the groups according to the random list obtained.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Safashahr St. - 1/1 Alley, Alley No. 4, No. 83

City

QOM

Province

Ghoush

Postal code

3713649373

Approval date

2020-07-21, 1399/04/31

Ethics committee reference number

IR.MUQ.REC.1399.154

Health conditions studied

1

Description of health condition studied

Covid19

ICD-10 code

U07.1

ICD-10 code description

Covid19

Primary outcomes

1

Description

Days of hospitalization

Timepoint

Daily

Method of measurement

View patient records

2

Description

Clinical signs

Timepoint

Before treatment and 2, 4, 7 days of treatment

Method of measurement

The severity of each of the patient's clinical symptoms is measured based on the visual analog scale in patients.

3

Description

Vital Signs

Timepoint

During hospitalization on a daily basis

Method of measurement

Monitoring device

Secondary outcomes

1

Description

Mortality

Timepoint

Daily patient follow-up

Method of measurement

View patient records

Intervention groups

1

Description

Intervention group: TherapIntervention group: Treatment protocol of the Ministry of Health + FT® powder, which contains a combination of black halibut powder and fennel with a natural sweetener and flavoring, which is prepared by a pharmacist. Pour a glass of beer and stir and sip.

Category

Treatment - Drugs

2

Description

Control group: This group includes patients who receive the routine medication regimen of the Ministry of Health and do not use the herbal powder that the intervention group receives; In this group, drugs such as remdesivir, corticosteroids, etc., which are commonly prescribed by doctors for patients with Quid 19, are used.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Shahid Beheshti Amir Al-Momenin Hospital

Full name of responsible person

Mohammad Mahdi Fallahpour khoshdel

Street address

Amir Al-Momenin Hospital,Shahid Beheshti Blvd,Qom,3719964797,IRAN.

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2

Recruitment center

Name of recruitment center

Kamkar Hospital

Full name of responsible person

Mohammad Mahdi Fallahpour khoshdel

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr.Ehsan Sharifpour

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No. 83,University Jihad Alley - Shahid Lotfi Niasar (Alley No. 4),Safashahr St,Qom,93456-37169,IRAN.

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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

Mohammad Mehdi Fallahpour Khoshdel

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Fallahpour Khoshdel

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Faculty of Pharmacy, University Campus, Azadi Square, Mashhad, 9177948954, IRAN.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Dr. Hossein Moradi Dehnavi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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