# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Nov 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 ۲. Intervention description: Control group: Treatment protocol of the Ministry of Health Classification: Control

**Main outcome variables**
1. Hospitalization days ۲. 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**
Ghoum

**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.
**City**
Qom
**Province**
Ghoum
**Postal code**
3719964797
**Phone**
+98 25 3612 2000
**Email**
bmc@muq.ac.ir

### 2

**Recruitment center**
**Name of recruitment center**
Kamkar Hospital
**Full name of responsible person**
Mohammad Mahdi Fallahpour khoshdel
**Street address**
19th Street (Bajak),Qom,3713614975,IRAN.
**City**
qom
**Province**
Ghoum
**Postal code**
3713614975
**Phone**
+98 25 3718 5000
**Email**
kamkar@muq.ac.ir
**Web page address**

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Ghoum University of Medical Sciences
**Full name of responsible person**
Dr.Ehsan Sharifipour
**Street address**
No. 83,University Jihad Alley - Shahid Lotfi Niasar (Alley No. 4),Safashahr St,Qom,93456-37169,IRAN.
**City**
Qom
**Province**
Ghoum
**Postal code**
93456-37169
**Phone**
+98 25 3285 2720
**Email**
res@mail.muq.ac.ir
**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

**Street address**
Faculty of Pharmacy, University Campus,Azadi Square,mashhad,9177948954,IRAN.
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177948954
**Phone**
+98 51 3180 1100
**Email**
fallahmohammad313@gmail.com

## 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
**Street address**
Qom University of Medical Sciences,Shahid Lavasani St,Qom,3713649373,IRAN..
**City**
Qom
**Province**
Ghoum
**Postal code**
3713649373
**Phone**
+98 25 3612 2058
**Email**
tebeiraniqom@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Ghoum University of Medical Sciences
**Full name of responsible person**
Dr. Samira Khani
**Position**
Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
medical School,Campus Complex,In front of Yadegar Imam Stadium,After campus,Blv.Ghadir,Qom,3736175513,IRAN.
**City**
Qom
**Province**
Ghoum
**Postal code**
3736175513
**Phone**
+98 25 3197 1121
**Email**
Skhani@muq.ac.ir

## 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