Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effects of Viroherb capsule and Fenugreek syrup derived from traditional Persian medicine on clinical and paraclinical outcomes and survival of patients with mild to moderate COVID-19 hospitalized in medical centers of Tehran University of Medical Sciences

Protocol summary

Study aim
Evaluation of the effect of Viroherb and Fenugreek in clinical and paraclinical outcomes and survival rate of patients with mild to moderate form of COVID-19

Design
Multicenter, randomized by block randomization, controlled, paralled group, open label clinical trial, sample size: 110

Settings and conduct
This study will be conducted in three medical centers of Tehran University of Medical Sciences (Amiralam, Ziaeeian, and Baharlou hospitals). Patients fulfilled inclusion criteria will be divided randomly in two groups: intervention group and control group. The study is open label. Duration of study is 5 days and outcomes will be measured at the beginning of study and on day 6.

Participants/Inclusion and exclusion criteria
patients aged 18 years or more with mild to moderate form of COVID-19

Intervention groups
Intervention group: Received medications according national guideline plus Viroherb capsule (2 caps bid) and Fenugreek syrup (10 cc qid) Control group: Received medications according national guideline

Main outcome variables
Clinical outcomes including fever, cough, dyspnea, myalgia; safety and adverse events of intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200402046923N1**
Registration date: **2020-04-09, 1399/01/21**
Registration timing: **registered_while_recruiting**
Last update: **2020-04-09, 1399/01/21**
Update count: **0**

Registration date
2020-04-09, 1399/01/21

Registrant information

Name
Roja Rahimi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 8899 0835

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-05, 1399/01/17

Expected recruitment end date
2020-05-06, 1399/02/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Viroherb capsule and Fenugreek syrup derived from traditional Persian medicine on clinical and paraclinical outcomes and survival of patients with mild to moderate COVID-19 hospitalized in medical centers of Tehran University of Medical Sciences

Public title

Effect of herbal capsule, Viroherb, and herbal syrup, Fenugreek in treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ability to understand and the willingness to sign a written informed consent document Aged 18 and more without sex restriction patients with mild to moderate form of COVID-19 according to national guideline not recieved any retroviral or immunostimulant medications in the past 3 months

Exclusion criteria:
pregnancy or lactation patients in whom COVID-19 in not confirmed Alcohol or drug addiction patients with hypertension patients with peptic ulcer patients with diabetes

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be randomly assigned to four blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment).The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of intervention and control (Assignment). Then based on blocks and allocation sequences medication will be given to patients.

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 Tehran University of Medical Sciences

Street address
Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1416753955

Approval date
2020-04-02, 1399/01/14

Ethics committee reference number
IR.TUMS.VCR.REC.1399.099

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Body temperature

Timepoint
At the beginning of the study and on day 6

Method of measurement
thermometer

2

Description
Adverse events

Timepoint
whole duration of study

Method of measurement
type and number of adverse event

3

Description
cough

Timepoint
At the beginning of the study and on day 6

Method of measurement
clinical judgement of physician

4

Description
dyspnea

Timepoint
At the beginning of the study and on day 6

Method of measurement
clinical judgement of physician

5

Description
Myalgia
Timepoint
At the beginning of the study and on day 6
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Liver enzymes (ALT, AST)
Timepoint
At the beginning of study and day 6
Method of measurement
Laboratory refferal

2

Description
Creatinine
Timepoint
At the beginning of study and day 6
Method of measurement
Laboratory refferal

3

Description
Blood Gas ABG
Timepoint
At the beginning of study and day 6
Method of measurement
Laboratory refferal

4

Description
Duration of hospital and ICU stay
Timepoint
At the end of study
Method of measurement
day(s)

5

Description
Complete blood count (CBC)
Timepoint
At the beginning of study and day 6
Method of measurement
Laboratory refferal

6

Description
Oxygen saturation
Timepoint
At the beginning of study and day 6
Method of measurement
Pulse oximetry

Intervention groups

1

Description
Intervention group: Medications in national guideline+ Viroherb capsule 500 mg 2 caps every 12 h + Fenugreek syrup 10 cc every 6 h
Category
Treatment - Drugs

2

Description
Control group: Medications in national guideline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralam hospital
Full name of responsible person
Ali Asadollahi-Amin
Street address
Saadi St., Inqelab Ave.,
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2

Recruitment center
Name of recruitment center
Ziaeian hospital
Full name of responsible person
Saeed Reza Jamali Moghaddam
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20 metri Abuzar, Abuzar Sq., Ghazvin St.
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3

Recruitment center

Name of recruitment center
Baharloo hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Web page address
http://vcr.tums.ac.ir

Grant name
COVID-19 grant
Grant code / Reference number
99-1-147-47262
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Roja Rahimi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data from primary and secondary outcomes of patients will be available on supplementary files of published paper.
When the data will become available and for how long
Available after publishing results
To whom data/document is available
Researchers
Under which criteria data/document could be used
It has not been made a decision yet.
From where data/document is obtainable
contact via Email Address: rojarahimi@gmail.com
What processes are involved for a request to access data/document
It has not been made a decision yet.
Comments