Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Pilot clinical trial to evaluate the effectiveness of Herbal Cyclotide complex syrup as a prevention of disease complications in people exposed to COVID-19 virus

Protocol summary

Study aim

Determination of the effectiveness of Cyclotide complex in the prevention of COVID-19 virus after exposure to patients with COVID-19 and comparison with the control group

Design

This clinical trial has a control group, and is performed in parallel, randomized, phase 2 to 3 groups on 60 healthy individuals in exposure to a patient with COVID-19. Randomization will be by block randomization (quadruple random blocks).

Settings and conduct

Participants (individuals in direct contact with patients with COVID-19 (including treatment staff working in isolated areas or housemates with patients with a negative PCR test) in the drug group should drink the syrup for fourteen days and They consume 20 ml every 8 hours. The control group did not receive any medication. The study place is Baqiyatallah Al-Azam Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. People over the age of 18 who have had close contact with a person with COVID-19 in the last 4 days and signed an informed consent form (close contact refers to those who live at home with an infected person or, depending on circumstances) Have an occupation less than two meters away from the infected person.) And have no previous or current history of COVID-19. Exclusion criteria: 1. Current COVID-19 disease, which is confirmed by PCR and clinical signs.

Intervention groups

The intervention groups will be two groups. The participants in the drug group use herbal syrup as a prevention and the control group does not use any specific drug.

Main outcome variables

RT-PCR result

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160131026298N4**
Registration date: **2020-08-04, 1399/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-04, 1399/05/14**
Update count: **0**

Registration date

2020-08-04, 1399/05/14

Registrant information

Name

Ahmad Reza Sharifi Olounabadi

Name of organization / entity

Baqiatallah University of Medical Science, Department of Traditional Iranian Medicine

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Pilot clinical trial to evaluate the effectiveness of Herbal Cyclotide complex syrup as a prevention of disease complications in people exposed to COVID-19 virus

Public title
Evaluation of the effectiveness of Cyclotide complex herbal syrup in preventing COVID-19 virus in exposed individuals

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
People over the age of 18 who have had close contact with a person with COVID-19 in the last 4 days and signed an informed consent form (close contact is defined as those who live at home with an infected person or depending on their employment situation in Less than two meters away from the infected person.) And have no previous or current history of COVID-19. Age between 18 and 70 years No previous diagnosis of COVID-19 (if possible, test negative for IgG and IgM antibodies.) Absence of symptoms such as fever, body aches, olfactory and taste disturbances, cough, shortness of breath, diarrhea in the last 1 month

Exclusion criteria:
Current incidence of COVID-19 is confirmed by PCR and clinical signs. History of autoimmune disease History of rheumatic disease Pregnancy and lactation Age under 18 years People sensitive to any component of the product People who can not follow up. Any clinical reason that may prevent you from entering the study. Do not take two doses of the drug

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be by block randomization (quadruple random blocks). Randomization units are individuals. 60 outpatients referred to the hospital emergency department are allocated in one of the two intervention and control groupsaccording to form of random string produced by online random allocation . This study is a non-concealed method and people in the intervention group will receive the intervention drug to prevent COVID-19 complications, but in the control group the drug is not used.

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 Baqiyatallah University of Medical Sciences

Street address
Baqiyatallah University of Medical Sciences, Shahid Nosrati Alley, Shaikh Bahai St., Vanak Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435916471

Approval date
2020-06-21, 1399/04/01

Ethics committee reference number
IR.BMSU.REC.1399.250

Health conditions studied

1

Description of health condition studied
COVID-19 viral disease

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Polymerase chain reaction (PCR) analysis result

Timepoint
At the beginning of the intervention and the day 14

Method of measurement
Polymerase chain reaction (PCR) analysis

2

Description
Liver function test result

Timepoint
At the beginning of the intervention and the day 14

Method of measurement

Measurement of aspartate aminotransferase (AST) and Alanine transaminase (ALT) factors

3

Description
Fragment D-dimer test result
Timepoint
At the beginning of the intervention and the day 14
Method of measurement
Blood test - Fragment D-dimer measurement

4

Description
Measurement of serum iron
Timepoint
At the beginning of the intervention and the day 14
Method of measurement
Blood test - Total iron binding capacity factor (TIBC) measurement

5

Description
COVID-19 Antibodies
Timepoint
At the beginning of the intervention and the day 14
Method of measurement
Measurement of IgG COVID-19 and IgM COVID-19 factors

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Consumable product includes herbal syrup composed of cyclopeptide fraction with Ziziphus spina-cristi and Pimpinela anisum hydroalcoholic extract and orange peel. The dose of the product is 20 ml every 8 hours after eating, which is prepared by Herbi Pharmed Pharmaceutical Company.
Category
Prevention

2

Description
Control group: do not use any drugs for prevention and only follow health protocols to prevent infection.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
AHMAD REZA SHARIFI OLOUNABADI
Street address
Mulla Sadra Street, Vanak Square, After Sheikh Baha'i, Baqiyatallah Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Gholamhosein Alishiri
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Baqiyatallah University, Third Floor, Vice-Chancellor for Research and Technology, Sheikh Bahai St, Mulla Sadra St,Vanak Square
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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
Herbi Pharmed pharmaceutical company
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shiva Shamshiri
Position
PhD Candidate
Latest degree
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Medical Pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Pay attention to organizational rules
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