Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of Aftogel strips on results of nasopharyngeal secretion PCR test in volunteers with positive test for COVID-19 virus

Protocol summary

Study aim

The effect of Aftogel strips on nasopharyngeal secretion PCR test in volunteers with positive test for COVID-19 virus

Design

This study is a double blind clinical trial which has two intervention and control groups which will be followed parallel. For randomization the patients will be located in quadruplet blocks in which 2 patients will receive the placebo and 2 patients will receive the tentative drug. After the study the codes of the drug will be opened and the results will be evaluated.

Settings and conduct

This study will be conducted in outpatient clinic. and the patients which are in stage 0 or 1 of the disease will be enrolled in the study. After selection on inclusion and exclusion criteria the patients will be located in one of the intervention and control group and the drugs which nominated by a code will be gave to the patients and after 5 days the COVID-19 RtPCR will be done on the patients. At the end the codes of the drug will be opened and the results of the tests will be evaluated.

Participants/Inclusion and exclusion criteria

Every patient with positive COVID-19 PCR and positive regard for our study will be accepted for study and if the patient who has one of the below condition will not be accepted for study: age below 18 years, on compliance for use our drug, old age, mental disturbance, user of other chemical and/or any traditional drug, the patients with underlying diseases such as hypertention, user of oral antiseptic solutions and the users of antiviral drugs.

Intervention groups

Strip of the drug (Aftogel) and placebo will give the patients and request them to consume the drugs 4 times a day. they should retain the drug in their mouth till to wash by their saliva and consume. Five days later the COVID-19 PCR test will be repeat on their nasopharyngeal secretions.

Main outcome variables

Positive or negative COVID-19 RtPCR test after consuming the drug.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041886N2**
Registration date: **2020-10-29, 1399/08/08**
Registration timing: **prospective**

Last update: **2020-10-29, 1399/08/08**
Update count: **0**

Registration date

2020-10-29, 1399/08/08

Registrant information

Name

Morteza Pourahmad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3322 0197

Email address

mortezapourahmad@yahoo.com

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 effect of Aftogel strips on results of nasopharyngeal secretion PCR test in volunteers with positive test for COVID-19 virus

Public title
Aftogel and COVID-19 PCR test

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Every body with positive COVID-19 Rt PCR Positive regard of the patient for cooperation

Exclusion criteria:
age< 18 years old No compliance for drug consumption Very old age patients and the patients with mental disturbance which can not cooperate. the patients who use other chemical and/or traditional drugs the patients with underlying diseases such as Hypertention the patients who use antiseptic oral solutions the patients who use antiviral drugs

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
the selected patients on inclusion and exclusion criteria in out patient clinic they will be located in nominated quadruplet blocks and in every block they will be located in placebo or intervention groups and will be received their own drugs.

Blinding (investigator's opinion)
Double blinded

Blinding description
For blinding the study; the palcebo and tentative drug will be used in same form and same boxes with different codes. the physician and the patient both , will not be informed about the drugs and only the pharmacist will be informed about the nature of the drugs. At the end of study the codes will be opened and the results will be evaluated.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Sofeh street

City
Isfahan

Province
Isfehan

Postal code
8189111491

Approval date
2020-09-21, 1399/06/31

Ethics committee reference number
IR.MUI.REC.1399.520

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1COVID

ICD-10 code description
U07.1 COVID-19, virus identified•U07.2 COVID-19, virus not identifiedoClinically-epidemiologically diagnosed COVID-19oProbable COVID-19 oSuspected COVID-19

Primary outcomes

1

Description
Negative COVID-19 Rt-PCR test after consuming the drug

Timepoint
5 days

Method of measurement
COVID-19 Rt- PCR test on nasopharyngeal secretions

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the patients with positive COVID-19 Rt PCR test will be selected and on random manner they will be treated with tentative drug (Aftogel strip) . This drug is made by Exir Danesh Asia pharmaceutical

company and contain the extract of black licorice. Black licorice contain 7% glycyrrhizin which has known antiviral effects. This drug is made in form of strip. In every time of use the patient will use 2 strip of this drug and will keep it in mouth for about 30 minutes till it resolves completely by saliva and be swallowed. The patient should repeat this using four times a day and for five days. The patients will be instructed about the method of use by physician.

Category

Treatment - Drugs

2

Description

Control group:the patients with positive COVID-19 Rt PCR test will be selected and on random manner they will be treated with placebo drug (as strip) . This drug is made by Exir Danesh Asia pharmaceutical company and will be in the same form as Aftogel strip (which will be used in intervention group) and will not contain the extract of black licorice. In every time of use the patient will use 2 strip of this drug and will keep it in mouth for about 30 minutes till it resolves completely by saliva and be swallowed. The patient should repeat this using four times a day and for five days. The patients will be instructed about the method of use by physician.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amin out patient clinic in Isfahan
Full name of responsible person
Dr. Morteza Pourahmad
Street address
Sofeh street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Exir Danesh Asia Pharmaceutical company
Full name of responsible person
Dr. Mohsen Saniei
Street address
Hakim Nezami street
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Isfehan
Postal code
8175978467
Phone
+98 31 3624 1167
Email
admin@exirpd.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Exir Danesh Asia 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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Morteza Pourahmad
Position
professor of infectious diseases
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
the article from this study will be published about the effect of the herbal drug (Aftogel) on the COVID-19 RtPCR test.
When the data will become available and for how long
Immediately after article publish.
To whom data/document is available
Every body
Under which criteria data/document could be used
No condition except the conditions of the publisher
From where data/document is obtainable
the article which will be published
What processes are involved for a request to access data/document
the procedure which will be prescribed by the publisher
Comments
No comment