Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of asafoetida on coronavirus outpatients: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim
Effect of asafoetida in coronavirus outpatients

Design
Randomized, blinded, placebo controlled clinical trial. Effect of asafoetia capsules in 40 patients which have inclusion criteria will be evaluated. Simultanously, 20 patients will take placebo. Medicine and placebo in the same form and package with the alphabetics A and B will be deliverd to physiciana and patients. Patients must take the capsules three times a day for 14 days

Settings and conduct
Randomized, blinded, placebo controlled clinical trial will be in mashhad . effect of asafoetida capsules in 40 patients with coronavirus disease which have inclusion criteria will be evaluated. Simultanously 20 patients will take placebo. Medicine and placebo in the same form and package with the alphabetics A and B will be deliverd to physician and patients. The patients must take the capsules three times a day for 14 days

Participants/Inclusion and exclusion criteria
Inclusion criteria: The outpatients in quarantine, take medicine, diagnosed for coronavirus disease according to clinic (fever, cough, myalgia) and paraclinic parameters (lymphopenia, increase CRP). Exclusion criteria: Sensitivity to licorice and it derivatives; below 18 and above 65 years old; hepato, renal or respiratory disorders; take cytotoxic, corticosteroid drugs; nursing or pregnant women

Intervention groups
En Effect of asafoetdida capsules in 40 patients (two groups) which have inclusion criteria will be evaluated. Simultanously 20 patients which have inclusion criteria will take placebo.

Main outcome variables
Time interval until lymphopenia improves Time interval until CRP normalizes Time interval until clinical symptoms improve (fever, cough and myalgia)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200413047053N1**
Registration date: **2020-04-15, 1399/01/27**
Registration timing: **prospective**

Last update: **2020-04-15, 1399/01/27**
Update count: **0**

Registration date
2020-04-15, 1399/01/27

Registrant information

Name
Mehrdad Iranshahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3180 1256

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iranshahim@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation the effect of asafoetida on coronavirus outpatients: A randomized, double-blind, placebo-controlled clinical trial

Public title
Evaluation the effect of asafoetida in the treatment of coronavirus infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Fever cough Myalgia lymphopenia CRP positive
Exclusion criteria:
Sensitivity to asafoetida and it derivatives Patients with hepatic disfunction Patients with renal disfunction Patients with respiratory disorders Patients who take cytotoxic or corticosteroid drugs Nursing women pregnant women
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in three stages: 1- Generation simple or limited randomization will be done based on a table of random numbers 2- Allocation concealment: which is done in the form of coded boxes (numbered drug containers) with a random sequence. In this method, a number of boxes with the same shape and size are numbered based on random sequences and contain drugs or placebo that have a completely similar appearance. 3- Execution of random allocation process: A: Identify the person who creates the random sequence B: A person who evaluates and registers researchers in terms of inclusion and exclusion criteria C: The person who assigned the participants to the groups: infectious diseases specialist The main researcher of the project, who creates a random sequence, does not interfere in other stages of randomization, including registration and allocation of participants, and the person involved in creating a random program is separate from other researchers.
Blinding (investigator's opinion)
Double blinded
Blinding description
the medicine in the form of similar capsule but with the alphabetics A or B will be delivered to physician and patients
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Ethics Committee of Mashhad University of Medical Sciences
Street address
Blv. Vakilabad2, school of pharmacy, 1368-91775
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Approval date
2020-04-13, 1399/01/25
Ethics committee reference number
IR.MUMS.REC.1399.071

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U07.1
ICD-10 code description
Covid-19

Primary outcomes

1

Description
lymphopenia
Timepoint
3 days, 1 week and 2 weeks after treatment
Method of measurement
Cell counter device

Secondary outcomes

1

Description
CRP level
Timepoint
3 days, 1 week and 2 weeks after treatment
Method of measurement
CRP kit

Intervention groups

1

Description
Intervention group1: In addition to the standard treatment regimen for covid-19, capsules which have aqueous 300 mg of Khorasan asafoetida will be given once a day for 2 weeks. asafoetida capsules are formulated at the Mashhad School of Pharmacy with the ineffective ingredients of Ovisil and Arozil. All patients in this group receive typical treatment including azithromycin and hydroxychloroquine.
Category
Treatment - Drugs

2

Description
Intervention group2: n addition to the standard treatment regimen for covid-19, capsules which have aqueous 300 mg of Fars asafoetida will be given once a day for 2 weeks. asafoetida capsules are formulated at the Mashhad School of Pharmacy with the ineffective ingredients of Ovisil and Arozil. All patients in this group receive typical treatment including azithromycin and hydroxychloroquine.
Category
Treatment - Drugs

3

Description
control group: this group receive placebo capsules exactly with similar characteristics to real drugs in intervention group. All patients in this group receive typical treatment including azithromycin and hydroxychloroquine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Dr. Dehghan Nayeri
Street address
Imam reza square
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۳۷۹۱۳۳۱۶
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DehghanMJ@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
daneshgah avenue
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9138813944
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+98 51 3854 1538
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mehrdad Iranshahi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
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Person responsible for scientific inquiries

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Position

Professor

Latest degree

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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

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

Not applicable