Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of Nigel-7 capsule and black seed mixture on COVID-19

Protocol summary

Study aim
Assessment of the effect of Iranian medicine product, Nigle 7 capsule and black seed mixture , on the symptoms of patients with covid-19 (Coronavirus 19 disease)

Design
This clinical trial has control group, and with parallel groups, One-way blind, randomized, phase 2 to 3 and is performed on 80 patients. Randomization method will be blocked randomization (Quaternary random blocks).

Settings and conduct
Patients in the drug group take the Iranian traditional drug for ten days (three capsules a day and ten grams of black seed mixture daily). Patient in control group use routine treatment (According to the protocol of the Ministry of Health). The study is performed in Baqiyatallah Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female patients 18 years old and older with COVID-19, Ground glass view at low-dose CT scan, Consciously completed consent form completed by the patient or the patient's supervisor. Exclusion criteria: History of pulmonary malignancy, History of asthma or COPD, History of Disabling disease or malignancy, Liver or kidney disorders.

Intervention groups
Intervention groups will be two ones.Patients in the intervention group will receive the intervention drug in addition to the routine treatment, but in control group, they will receive routine treatment.

Main outcome variables
3D lung CT Scans, dyspnea, cough, CBC diff

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160131026298N6**
Registration date: **2020-09-08, 1399/06/18**
Registration timing: **prospective**

Last update: **2020-11-01, 1399/08/11**
Update count: **2**

Registration date
2020-09-08, 1399/06/18

Registrant information

Name
Ahmad Reza Sharifi Olounabadi

Name of organization / entity
Baqiatallah University of Medical Science, Department of Traditional Iranian Medicine

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-05, 1399/08/15

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Nigel-7 capsule and black seed mixture on COVID-19

Public title

Evaluation of the effectiveness of Nigel-7 capsule and black seed mixture on corona

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male or female patients 18 years old and older with Coronavirus Disease 2019 (COVID-19) Ground glass view at low-dose CT scan Consciously completed consent form completed by the patient or the patient's supervisor

Exclusion criteria:
History of pulmonary malignancy History of asthma or COPD History of Disabling disease or malignancy Liver or kidney disorders

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method will be blocked randomization (Blocks of size 4). Randomization units are individuals. Eighty outpatients referred to the hospital emergency department are randomly assigned to one of the two intervention and control groups according to form of random string produced by online random allocation .

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
2020-03-29, 1399/01/10

Ethics committee reference number
IR.BMSU.REC.1399.157

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.2

ICD-10 code description
U07.2 COVID-19, virus not identified, COVID-19

Primary outcomes

1

Description
Measurement of cough severity

Timepoint
Day 1 before and at the end of treatment

Method of measurement
Cough scoring form

2

Description
Severity of shortness of breath

Timepoint
Day 1 before and at the end of treatment

Method of measurement
Shortness Of Breath With Daily Activity (SOBDA) Questionnaire

3

Description
Lung radiologic changes

Timepoint
At beginning and end of the study

Method of measurement
Chest CT scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention groups will be two ones. Patients in the intervention group will receive the intervention drug (three capsules a day and ten grams of black seed mixture daily) that is made by Talaye sabze tooba company; in addition to the routine treatment

(Azithromycin 250 mg daily for 10 days and Naproxen 250 mg twice a day for 10 days) .

Category

Treatment - Drugs

2

Description

Control group: The control group will receive the routine treatment (Azithromycin 250 mg daily for 10 days and Naproxen 250 mg twice a day for 10 days) .

Category

Placebo

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

Street address

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?

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ahmad Reza Sharifi Olounabadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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
Undecided - It is not yet known if there will be a plan to make this available