

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the effect of using the GreenNature Deep Lung Support product on the clinical condition of patients with COPD exacerbation

Protocol summary

Study aim

Investigating the effect of using the GreenNature Deep Lung Support product on the clinical condition of patients with COPD exacerbation

Design

The present study is a clinical trial with one control group and two intervention groups, with parallel and double-blind groups, randomized with a sample size of 60 patients. After randomly assigning the patients to three groups, the patients of the first group will receive placebo, the patients of the second group will receive one capsule of deep lung support daily, and the patients of the third group will be given three doses of this supplement daily. Then, on the first day and the day of discharge (ten days later), blood samples will be collected from all patients and clinical symptoms and factors including TNF- α , IL-8, CDC, and CRP will be compared in patients of three groups.

Settings and conduct

The present study is conducted as a clinical trial on patients with COPD exacerbation referred to Masih Deneshvari Hospital in Tehran. All patients who meet the inclusion criteria will be placed in one of the three study groups after providing full explanations and obtaining written consent.

Participants/Inclusion and exclusion criteria

Inclusion criteria include COPD exacerbation grade D, BMI > 18 < 21 and smoking. Exclusion criteria include the patient's lack of consent to participate in the study, defects in the file, and drug sensitivity.

Intervention groups

The patients of the control group will receive placebo, the patients of the first intervention group will be given one capsule of deep lung support daily, and the patients of the second intervention group will be given three doses of this supplement daily.

Main outcome variables

Borg scale, MMRC, cough, sputum, PH, PCO₂, HCO₃, lymphocyte, neutrophil, urea, creatinine, AST, ALT, ALP,

IL-6, ferritin, D-dimer, LDH T, procalcitonin, TNF- α , IL-8, CRP, ESR, WBC, RBC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047727N5**

Registration date: **2023-02-21, 1401/12/02**

Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Maryam Sadat Mirenayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 5050

Email address

mirenayat@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using the GreenNature Deep Lung Support product on the clinical condition of patients with COPD exacerbation

Public title

Investigating the effect of using GreenNature Deep Lung Support product in COPD patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COPD exacerbation grade D Smoking BMI greater than 18 and less than 21

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method, individual randomization unit and random number table randomization tool. For randomization, we use a table consisting of random digits from 0 to 9. Each of the figures in this table is repeated the same on average. We start from the first row of the table and move down row by row. For three treatments, we put numbers 1 to 3 for treatment A, numbers 4 to 6 for treatment B, and numbers 7 to 9 for treatment C. We continue the above process until three groups are completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to prevent any possible complications, the doctor and clinical caregiver are fully aware of the assignment of treatment groups. Participating patients and researchers responsible for data collection and analysis are not aware of the allocation of different study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Dr. Masih Daneshvari Hospital, Darabad, Shahid Bahonar St.

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.SBMUNRITLD.REC.1401.123

Health conditions studied**1****Description of health condition studied**

Chronic obstructive pulmonary disease

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes**1****Description**

AST

Timepoint

The first day and the next ten days

Method of measurement

Laboratory tests

2**Description**

ALT

Timepoint

The first day and the next ten days

Method of measurement

Laboratory tests

3**Description**

IL-6

Timepoint

The first day and the next ten days

Method of measurement

Laboratory tests

4

Description

Ferritin

Timepoint

The first day and the next ten days

Method of measurement

Laboratory tests

5

Description

Procalcitonin

Timepoint

The first day and the next ten days

Method of measurement

Laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description

Control group: patients in the control group receive a placebo capsule daily.

Category

Placebo

2

Description

Intervention group: Patients of this group receive one deep lung support capsule made by DayGgen Pharmed company orally and once a day. The chemical composition of this medicine includes the dry extract of Andrographis paniculata, Echinacea purpurea, Eriobotrya japonica, Fritillaria cirrhosa, Olea europaea, Scutellaria baicalensis, and taraxacum officinale.

Category

Treatment - Drugs

3

Description

Intervention group: The patients of this group receive three capsules of deep lung support made by DayaGen Pharmed orally three times a day. The chemical composition of this medicine includes the dry extract of Andrographis paniculata, Echinacea purpurea, Eriobotrya japonica, Fritillaria cirrhosa, Olea europaea, Scutellaria baicalensis, and taraxacum officinale.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Masih Deneshvari Hospital

Full name of responsible person

Maryam Sadat Mirenayat

Street address

Masih Daneshvari Hospital, Daarabad

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

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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

DAYAGEN pharmed

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Sadat Mirenayat

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Researcher

Latest degree

Master

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Biotechnology

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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

There is no further information.

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