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-a, 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)

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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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mirenayat@sbmu.ac.ir

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

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Person responsible for updating data

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Full name of responsible person
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Researcher

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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