Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessing of efficacy of IMPOHelzavid herbal compound on mortality of hospitalized patients with community-acquired pneumonia

Protocol summary

Study aim

Determining the efficacy of IMPOHelzavid herbal compound on mortality rate of hospitalized patients with community acquired pneumonia.

Design

This triple-blind, phase 2 clinical trial will be conducted in 60 patients with community-acquired pneumonia. Patients are randomly assigned in 15 blocks of 4 patients. Then each patient in the block receives a herbal or placebo capsule coded A or B. In this way, 30 patients will be received a herbal combination and 30 a placebo. The duration of treatment is 3 days.

Settings and conduct

This study will be carried out in Kowsar hospital affiliated to Semnan University of Medical Sciences. The intervention group received the herbal combination of impohelzavid IMPOHelzavid herbal compound in addition to conventional treatment and the control group received placebo in addition to conventional treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with community acquired pneumonia Age 40 to 80 years of age who have the ability to take oral product Exclusion criteria: patients with severe dyspnea require mechanical ventilation or hospitalization in intensive care units, and patients with severe underlying diseases and pregnant women.

Intervention groups

The intervention group received 500 mg of the IMPOHelzavid herbal compound as 2 capsules every 12 hours for up to 72 hours. The control group received two capsules of the same color containing breadcrumbs every 12 hours for 72 hours. To equalize the smell and taste of the capsules in each of the two groups, 2 milligrams of bitter watermelon powder and 5 milligrams of beet extract powder are added to each 1 gram of drug content or placebo.

Main outcome variables

Duration of hospitalization, need for mechanical ventilation, and mortality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N18**
Registration date: **2023-08-22, 1402/05/31**
Registration timing: **prospective**

Last update: **2023-08-22, 1402/05/31**
Update count: **0**

Registration date

2023-08-22, 1402/05/31

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing of efficacy of IMPOHelzavid herbal compound on mortality of hospitalized patients with community-acquired pneumonia

Public title

Effect of IMPOHelzavid herbal compound on hospitalized patients with community-acquired pneumonia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with pneumonia

Exclusion criteria:

Patients admitted in ICU Patients with uncontroled diabetes, hypertension and cardiovascular, respiratory, hepatic and renal underlying diseases

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups is done by block randomization (four blocks) in Excel software. In this software, treatment and control groups are placed as every other one at first column. Four blocks are placed in the next column. Finally, the random numbers created by the random number generation software are placed. Then we will arrange the numbers based on the block and random numbers columns.

Blinding (investigator's opinion)

Double blinded

Blinding description

The herbal combination of IMPOHelzavid and placebo are packaged in identical packages with A or B code labels and are provided to the clinical care provider for administration. The doctor, nurse, patient, those responsible for data collection and those who evaluate the outcome are unaware of the drug and placebo groups. Only the expert in charge of the formulation who did the packaging knows the contents of the packages or the code code A or B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Basij Blvd.

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.SEMUMS.REC.1402.082

Health conditions studied

1

Description of health condition studied

Community acquired pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified organism

Primary outcomes

1

Description

Blood oxygen saturation

Timepoint

At beginning and daily every 6 hours up to end of the study

Method of measurement

Pulse Oximeter

2

Description

Cough

Timepoint

At beginning and daily every 12 hours up to end of the study

Method of measurement

Cough evaluating questionnaire based on Visual Analog Scales

3

Description

Dyspnea

Timepoint

At beginning and daily every 12 hours up to end of the study

Method of measurement

Shortness of Breath with Daily Activities questionnaire (SOBDA)

Secondary outcomes

1

Description

Hospitalization

Timepoint

During the study

Method of measurement

Number of hospitalization day

2

Description

Need to mechanical ventilation

Timepoint

During the study

Method of measurement

If mechanical ventilation is required, the patient will be excluded from the study.

3

Description

Mortality

Timepoint

During the study

Method of measurement

The number of expired patients

Intervention groups

1

Description

Intervention group: They will receive 500 mg of the IMPOHelzavid herbal compound as 2 capsules every 12 hours for up to 72 hours. IMPOHelzavid contains a mixture of medicinal plants, including Wormwood (aerial parts), Marzangu (aerial parts), Drimia (root), Licorice (root), Hedge nettle (aerial parts), Withania somnifera (root) and Dianthus (flower). Extraction, lyophilization, encapsulation and packaging have been carried out in the Medicinal Plants Research Institute affiliated to The Academic Center for Education,Culture and Research (ACECR) under the supervision of the Food and Drug Organization.

Category

Treatment - Drugs

2

Description

Control group: They will receive two capsules, containing breadcrumbs every 12 hours for 72 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Fatemeh Taghavi Raeisi

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Amin Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Farhad Malek

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pulmonology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Research results are published in the form of articles.

When the data will become available and for how long

The article will be published about six months after the completion of the study.

To whom data/document is available

There is no objection or prohibition for public use of the published article.

Under which criteria data/document could be used

The use of data with reference to the source is unrestricted.

From where data/document is obtainable

Vice Chancellor for Research, Semnan University of Medical Sciences of direct contact with person responsible for scientific inquiries.

What processes are involved for a request to access data/document

To view the report of this research, after sending the request, the Vice Chancellor for Research of Semnan University of Medical Sciences will follow up and inform.

Comments