

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 23 3343 7844

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mehrdadzahmatkesh@semums.ac.ir

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		Secondary Ids	empty
Public title	Effect of IMPOHelzavid herbal compound on hospitalized patients with community-acquired pneumonia	Ethics committees	
Purpose	Supportive	<u>1</u>	
Inclusion/Exclusion criteria		Ethics committee	
Inclusion criteria:	Patients with pneumonia	Name of ethics committee	Ethics committee of Semnan University of Medical Sciences
Exclusion criteria:	Patients admitted in ICU Patients with uncontrolled diabetes, hypertension and cardiovascular, respiratory, hepatic and renal underlying diseases	Street address	Basij Blvd.
Age	From 40 years old to 80 years old	City	Semnan
Gender	Both	Province	Semnan
Phase	2	Postal code	3514799442
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor - Data analyser	Approval date	2023-07-31, 1402/05/09
Sample size	Target sample size: 60	Ethics committee reference number	IR.SEMUMS.REC.1402.082
Randomization (investigator's opinion)	Randomized	Health conditions studied	
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.	<u>1</u>	
Blinding (investigator's opinion)	Double blinded	Description of health condition studied	Community acquired pneumonia
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.	ICD-10 code	J18.9
Placebo	Used	ICD-10 code description	Pneumonia, unspecified organism
Assignment	Parallel	Primary outcomes	
Other design features		<u>1</u>	
		Description	Blood oxygen saturation
		Timepoint	At beginning and daily every 6 hours up to end of the study
		Method of measurement	Pulse Oximeter
		<u>2</u>	
		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
		<u>3</u>	
		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
Street address
 Amin Avenue
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 3519899951
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Email
 F_taghavi759@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
 Semnan University of Medical Sciences
Full name of responsible person
 Majid Mirmohammadkhani
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 majidmirmohammadkhani@yahoo.com
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
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Person responsible for updating data

Contact

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Latest degree
Bachelor
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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