

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of the effect of HemoHIM supplement for the prevention of ventilator associated pneumonia in critically ill patients

Protocol summary

Study aim

Evaluation of the effect of HemoHIM supplement for the prevention of ventilator associated pneumonia in critically ill patients

Design

A randomized, controlled clinical trial with parallel groups was designed among 30 patients (15 patients in each HemoHIM and control groups). Restricted randomization with permuted block method by computer was used to allocate patients to these 2 groups.

Settings and conduct

This randomized clinical trial was designed to evaluate the HemoHIM supplement's effect for preventing ventilator-associated pneumonia among 30 patients admitted to the intensive care unit of Kashani hospital in Isfahan, Iran, in two parallel groups. After gaining informed consent patients are allocated to HemoHIM and control group based on restricted randomization with permuted block method. In the intervention group, in addition to standard prevention strategies, a packet of HemoHIM supplement is used daily and orally for 7 days. But, in the control group, only standard prevention strategies were conducted. All patients were followed daily to ventilator-associated pneumonia based on clinical pulmonary infection score (CPIS) criteria for 14 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gaining informed consent, adult patients undergoing mechanical ventilation for more than 48 hours. Exclusion criteria: Diagnosis of acute respiratory distress syndrome or pneumonia at intensive care unit (ICU) admission; Existence of immunodeficiency and leukopenia

Intervention groups

Intervention group: In addition to standard prevention strategies, a packet of HemoHIM supplement containing 20 cc of herbal extract is used daily and orally for 7 days. Control group: Only standard prevention strategies were conducted.

Main outcome variables

Incidence of ventilator-associated pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150221021159N6**

Registration date: **2021-04-04, 1400/01/15**

Registration timing: **prospective**

Last update: **2021-04-04, 1400/01/15**

Update count: **0**

Registration date

2021-04-04, 1400/01/15

Registrant information

Name

Shadi Farsaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2618

Email address

farsaei@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of HemoHIM supplement for the prevention of ventilator associated pneumonia in critically ill patients

Public title
The effect of HemoHIM supplement for the prevention of ventilator associated pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Gaining informed consent Adult patients undergoing mechanical ventilation for more than 48 hours
Exclusion criteria:
Diagnosis of acute respiratory distress syndrome or pneumonia at intensive care unit (ICU) admission
Existence of immunodeficiency and leukopenia

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Restricted randomization with the permuted block method was used to create the random sequence and balance the number of allocated samples in each group (control and HemoHIM). The computer program was used for a random sequence in blocks of 2, 4, and 6. Each block has an equal number of control and HemoHIM groups. It is written on the cards and placed respectively for hiding in locked opaque packets. A packet was selected for each patient according to the study recruitment, which determines the related study group.

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 Isfahan University of Medical sciences
Street address
Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hizar jarib street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Approval date
2021-03-03, 1399/12/13
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.767

Health conditions studied

1

Description of health condition studied
Ventilator associated pneumonia
ICD-10 code
J95.851
ICD-10 code description
Ventilator associated pneumonia

Primary outcomes

1

Description
Incidence of ventilator associated pneumonia
Timepoint
Evaluation of the occurrence of ventilator associated pneumonia daily, during 14 days after study recruitment
Method of measurement
Calculate the clinical pulmonary infection score (CPIS) table

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the standard care conducted in ICU for preventing ventilator-associated pneumonia, a packet of HemoHIM supplement containing 20 cc of herbal extract manufactured by KolmarBNH Sun Biotech Business (SBT) company of Korea is used daily and orally for 7 days.
Category
Prevention

2

Description

Control group: Receive standard care of the intensive care unit to prevent ventilator-associated pneumonia, such as head elevation

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Hosein Mahjubipour

Street address

No.53, 29th Alley , Chahar Bagh Paeen Ave., Isfahn, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou Javanmard

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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

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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