Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Isfehan

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
City
Isfahan
Province
Isfehan
Postal code
8148614481
Phone
+98 31 3792 7071
Email
farsaei@pharm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjou Javanmard
Street address
Gostaresh Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hizarjarib st.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
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
Street address
Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezarjerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7071
Email
Farsaei@pharm.mui.ac.ir

Person responsible for scientific 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
Street address
Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezarjerib St.
City
Isfahan
Province
Isfehan
Postal code

8174673461

Phone

+98 31 3792 7071

Email

Farsaei@pharm.mui.ac.ir

Person responsible for updating data

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

Street address

Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezarjerib St.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 7071

Email

Farsaei@pharm.mui.ac.ir

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