

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of the effect of enteral administration of glutamine supplement for the prevention of ventilator associated pneumonia in critically ill patients

Protocol summary

Study aim

Evaluation of the effect of enteral administration of glutamine supplement for the prevention of ventilator associated pneumonia in critically ill patients

Design

Randomized clinical trial with a parallel group was designed among 40 patients (20 patients in each glutamin and control group). Simple randomization was used to allocate patients to these 2 groups.

Settings and conduct

This randomized, clinical trial was designed to evaluate the effect of the enteral glutamin on the prevention of ventilator associated pneumonia among 40 patients, in two parallel groups. Patients were randomly allocated to glutamin and control group. In intervention group, in addition to standard prevention strategies, 40 gram oral powder of glutamin was administered daily for 7 days. But, in control group only standard prevention strategies were conducted. All patients were followed daily for occurrence of ventilator associated pneumonia base on CPIS criteria for 14 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients undergoing mechanical ventilation for 48 hours Exclusion criteria: Diagnosis of acute respiratory distress syndrome or Pneumonia at intensive care unit (ICU) admission

Intervention groups

Intervention group: In addition to standard prevention strategies, forty milligram of glutamin powder was administered via enteral rout, for 7 days. Control group: Only standard prevention strategies were conducted.

Main outcome variables

Score calculated based on clinical pulmonary infection score (CPIS) table

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150221021159N5**

Registration date: **2020-06-30, 1399/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-30, 1399/04/10**

Update count: **0**

Registration date

2020-06-30, 1399/04/10

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

2019-10-23, 1398/08/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

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

Public title
The effect of enteral administration of glutamine supplement for the prevention of ventilator associated pneumonia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients undergoing mechanical ventilation for 48 hours
Exclusion criteria:
Diagnosis of acute respiratory distress syndrome or Pneumonia at intensive care unit (ICU) admission

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Glutamin and control group were written in 2 separated cards and placed in the box. One of these 2 cards was randomly selected when each patient was recruited to the study, and patient was allocated to glutamin or control group, based on selected card.

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
2019-07-09, 1398/04/18
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.215

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

Prevention 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: Forty milligram of glutamin powder was administered via enteral rout, for 7 days.

Category

Prevention

2

Description

Control group: No intervention was conducted.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

AlZahra hospital

Full name of responsible person

Shadi Farsaei

Street address

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

City

Isfahan

Province

Isfahan

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

Isfahan

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?

Yes

Title of funding source

Esfahan 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

Isfahan

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

Isfahan

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

Isfahan

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