

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Vitamin C administration in patients mortality with severe pneumonia in ICU

Protocol summary

Study aim

In this study, on patients with severe pneumonia admitted to the intensive care unit, the effect of prescription vitamin C on the mortality rate of patients will be examined.

Design

A simple randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

In a double-blind clinical trial, 80 patients admitted to the ICU for severe pneumonia were determined according to the relevant criteria and enrolled randomly into two groups of 40 patients receiving standard and routine treatments and group receiving standard and routine treatments in addition to vitamin C. The study will be conducted at Sina Hospital in Tabriz and patients, clinical caregivers, and data analysts will be unaware of grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients with severe pneumonia based on the criteria and exclusion criteria included patients who were unable to survive more than 24 hours due to end stage co-morbidities or clinical deterioration. Patients who consumed up to 48 hours prior to admission to unknown doses of vitamin C, patients who had a history of warfarin medication 24 hours prior to the study, with or without their consent, or their peers, or patients who did not receive informed consent from the patient or family. serum creatinine is above 1.5, patients below 18 and above 90 years, patients with G6PD deficiency, patients with bleeding disorders, and patients with a history of renal oxalate stones will be excluded.

Intervention groups

Intervention group: Group who receive standard and routine treatment of pneumonia in addition to vitamin C (50mg/kg/day) Control group: Group who receive standard and routine treatment of pneumonia in addition to the same volume of normal saline

Main outcome variables

Mortality : Mechanical ventilation free days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043030N1**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

seied hadi saghaleini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-15, 1398/02/25

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Vitamin C administration in patients mortality with severe pneumonia in ICU

Public title

Effect of Vit C in severe pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients who have been diagnosed with severe pneumonia criteria

Exclusion criteria:

Patients who are not able to survive for more than 24 hours because of end-stage or clinical deterioration

Patients with their own dissatisfaction or the inability to obtain informed consent from the patient or family of patients

Patients under the age of 18 and over

Patients who have had warfarin use 24 hours before study

Patients who received up to 48 hours prior to admission

Undetermined vitamin C

Patients with bleeding disorders

Patients with G6PD deficiency

Patients with primary creatinine above 1.5

Patients with a history of kidney oxalate stones

AgeFrom **18 years** old to **90 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 20 units of 4 blocks will be selected so that we consider having 40 people in control group (A) and 40 people in intervention group (B). Therefore, we will do block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, clinical caregivers, and data analyzers will not aware of grouping .

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Science, Gholghasht street, Azadi street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.TBZMED.REC.1398.482

Health conditions studied**1****Description of health condition studied**

Effects of vitamin C administration in patients mortality with severe pneumonia in ICU

ICD-10 code

A40.3

ICD-10 code description

Sepsis due to Streptococcus pneumoniae

Primary outcomes**1****Description**

Frequency of mortality

Timepoint

28 days mortality rate

Method of measurement

Sequential organ failure Assessment score

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The recipient group will receive standard and routine pneumonia treatments including respiratory support and serum therapy and mechanical ventilation, empirical antibiotic therapy and subsequent

antibiotic therapy with appropriate dose based on the results of cultures and relevant antibiograms, respectively, for 14 days. Appropriate doses of bronchodilator (salbutamol) and inhaled anticholinergic (Ipratropium bromide) mucolytic therapy (ampoule n-acetylcysteine) will also be used to treat these patients in addition to vitamin C (50mg / kg). The prescribed dose of Vitamin C 50mg / kg / day will be divided into 4 equal doses, each administered at 6 hours interval for 30 minutes at 50 ml DW5 serum (which will be included in the patient's serum intake) will continue for 4 days

Category

Treatment - Drugs

2

Description

Control group: Group who will receive standard and routine pneumonia treatments including respiratory support and serum therapy and mechanical ventilation, empirical antibiotic therapy and subsequent antibiotic therapy with appropriate dose based on the results of cultures and relevant antibiograms, respectively, for 14 days. Appropriate doses of bronchodilator (salbutamol) and inhaled anticholinergic (Ipratropium bromide) mucolytic therapy (ampoule n-acetylcysteine) will also be used to treat these patients in addition to the same volume of normal saline in intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr.Seied Hadi Saghaleini

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East Azerbaijan Province, Tabriz, North West Medical Toxicology Center ,Sina hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Joyban

Street address

Vice chancellor for research, Daneshgah Street, Tabriz

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Seyed Hadi Saghaleini

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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East Azerbaijan Province, Tabriz, North West Medical Toxicology Center,Sina Hospital

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

all collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data.

From where data/document is obtainable

Dr .Seyed Hadi Saghaleini Sina Hospital Azadi Street,
Sina Hospital, Tabriz East Azarbaijan Islamic Republic of
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What processes are involved for a request to access data/document

Correspondence through email only

Comments