Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The combined effect of statin and vitamins in patients with septic shock, a double-blind clinical trial study

Protocol summary

Study aim
Reducing mortality in patients with septic shock
Design
Our study is a phase 3 clinical trial that deals with the effect of two drugs, vitamin C and atorvastatin, on the mortality of septic shock. In reducing the mortality of septic shock, we have chosen two groups of 30 as a basis, and the patients are entered into these three groups using a random table, and by examining these two groups, we obtain the main sample size.
Settings and conduct
Our study group of patients with septic shock who will be hospitalized in Labafinejad internal intensive care unit are selected and the patients are given two study drugs that are completely matched in terms of shape, size and packaging and are cared for by the doctor. Special tests that do not know the type of drug received will be collected
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients over 18 years old Patients with septic shock who are under norepinephrine infusion Patients with a positive infectious culture Patients admitted to the intensive care unit Exclusion criteria: Dissatisfaction Death of the patient during the study
Intervention groups
In the intervention group, vitamin C is prescribed as one gram three times a day for 5 days, and atorvastatin 40 mg daily will be gavage to the patient.
Main outcome variables
The mortality rate of patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190215042716N3**
Registration date: **2022-11-29, 1401/09/08**
Registration timing: **prospective**
Last update: **2022-11-29, 1401/09/08**
Update count: **0**
Registration date
2022-11-29, 1401/09/08

Registrant information
Name
navid shafigh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8801 3378
Email address
n.shafigh@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-12-22, 1401/10/01
Expected recruitment end date
2023-05-24, 1402/03/03
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The combined effect of statin and vitamins in patients with septic shock, a double-blind clinical trial study

Public title
The combined effect of statin and vitamins in patients with septic shock, a double-blind clinical trial study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Patients admitted to the intensive care unit Patients with septic shock

Exclusion criteria:

Age less than 18 years Lack of legal consent from the patient's companions

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the inclusion criteria were selected by a random number table and by reading numbers from left to right. The numbers were between 00 and 30 in group A (intervention) (and the patients whose numbers were between 31 and 60 in group B (placebo)) The table of random numbers is a table, it is a collection of numbers that are generated completely randomly without a specific pattern or order. It is in the form of a table, and in order to use this table, the researcher must determine the direction of reading the numbers in advance and consider a default for the numbers of each intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The nurses will give the drugs of the 2 groups, which are completely matched in terms of shape, color and packaging, to the patients, and after that, the special care nurse, who has no knowledge of the received medicine, will collect the requested parameters of the patients, and then The information in two groups will be given to the data analyst and will be analyzed

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid beheshti University od Medical Sciences

Street address

Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2022-11-19, 1401/08/28

Ethics committee reference number

IR.SBMU.MSP.REC.1401.410

Health conditions studied

1

Description of health condition studied

Septic Shock

ICD-10 code

R57.2

ICD-10 code description

Severe sepsis with septic shock

Primary outcomes

1

Description

The mortality rate of patients

Timepoint

The time of discharge of the patient from the intensive care unit

Method of measurement

The number of group deaths

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, vitamin C is prescribed as one gram three times a day for 5 days, and atorvastatin tablets 40 mg daily will be gavage for the patient.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinezhad Hospital

Full name of responsible person
Navid shafigh
Street address
9th Boostan, Pasdaran St.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2254 9010
Email
Lamc@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Navid Shafigh
Street address
Shahid Shahriari Square, Daneshjo Boulevard, Shahid Chamran Highway,
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2990 2233
Email
n.shafigh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Navid Shafigh
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
N0.15, 26 Ave ,27 Ave, Kordestan Blvd , Tehran Yown
City
Tehran
Province
Tehran
Postal code
1437714791
Phone
+98 21 8801 3378
Fax
Email
n.shafigh@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Navid Shafigh
Position
Consultant
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
N0.15, 26 Ave ,27 Ave, Kordestan Blvd , Tehran Yown
City
Tehran
Province
Tehran
Postal code
1437714791
Phone
+98 21 8801 3378
Fax
Email
n.shafigh@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Navid Shafigh
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology

Street address
N0.15, 26 Ave ,27 Ave, Kordestan Blvd , Tehran Yown
City
Tehran
Province
Tehran
Postal code
1437714791
Phone
+98 21 8801 3378
Fax
Email
n.shafigh@sbmu.ac.ir

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
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
Title and more details about the data/document
The whole potential data after being unidentifiable is published
When the data will become available and for how long
One year
To whom data/document is available
Medical Society
Under which criteria data/document could be used
Contributing to studies
From where data/document is obtainable
Email: n.shafigh@sbmu.ac.ir
What processes are involved for a request to access data/document
Tho months
Comments