

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 of 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

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9th Boostan, Pasdaran St.

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**Postal code**

1956944413

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Navid Shafigh

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**Fax****Email**

n.shafigh@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

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Shahid Shahriari Square, Daneshjo Boulevard, Shahid Chamran Highway,

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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**

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****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

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Navid Shafigh

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**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**