Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of high doses of intravenous vitamin C on coagulation factors and vascular endothelium in sepsis patients

Protocol summary

Study aim

Effect of High Doses of Vitamin C on Coagulation Factors and Vascular endothelium in Sepsis Patients

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 50 patients. Block Randomization was used for randomization.

Settings and conduct

This RCT study will be conducted in the special care units of Sinai Hospital in 2018-2019. Adult patients with sepsis who are hospitalized in the intensive care unit and meet the inclusion criteria, after obtaining the form Consent will be included in the study. Patients will be randomly divided into two groups of 25 people - 1:1 through Block Randomization. • The first group, in addition to the standard treatment, 25 mg/kg of vitamin C as a bolus every six hours for 72 hours. will receive and • The second group will receive only the standard treatment. a sample is taken from them and checked in the laboratory

Participants/Inclusion and exclusion criteria

Entry requirements: Having sepsis according to the criteria stated in the Surviving Sepsis Campaign 2016 Guideline based on SOFAScore Non-entry conditions: Age less than 18 years • Age above 80 years • pregnancy • kidney failure: AKI according to the definition of KDIGO guidelines • Receiving other antioxidants 24 hours before and during the study (NAC, melatonin and selenium) • Receiving intravenous fibrinogen • Receive intravenous PCC • Receiving heparin with a therapeutic dose INR˃1.5 • (PLT˂100000) Thrombocytopenia • Patients receiving warfarin • Hemochromatosis patients Chronic renal failure (GFR<40) • More than 48 hours have passed since the onset of sepsis

Intervention groups

In addition to the standard treatment, the first group will receive 25 mg/kg of vitamin C as a bolus every six hours for 72 hours. The second group will receive only the standard treatment.

Main outcome variables

Syndecan-1,CRP/ALB ratio, ACR, FDP/D-Dimer Ratio, Antithrombin 3, fibrinogen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190718044264N1**
Registration date: **2022-12-03, 1401/09/12**
Registration timing: **retrospective**

Last update: **2022-12-03, 1401/09/12**
Update count: **0**

Registration date

2022-12-03, 1401/09/12

Registrant information

Name

Kiumarth Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2226 4452

Email address

drkiumarthamini1364@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-19, 1399/01/31

Expected recruitment end date

2022-08-19, 1401/05/28

Actual recruitment start date

2020-04-19, 1399/01/31

Actual recruitment end date

2022-08-19, 1401/05/28

Trial completion date
2022-08-19, 1401/05/28

Scientific title
Investigating the effect of high doses of intravenous vitamin C on coagulation factors and vascular endothelium in sepsis patients

Public title
Effect of High Doses of intravenous Vitamin C on Coagulation Factors and Vascular endothelium in Sepsis Patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having sepsis according to the criteria stated in the surviving sepsis campaign 2016 Guideline based on SOFAScore

Exclusion criteria:
Age less than 18 years Age above 80 years pregnancy Suffering from kidney failure: AKI according to the definition of KDIGO guidelines Receiving other antioxidants 24 hours before and during the study (NAC, melatonin and selenium) Receive intravenous fibrinogen Receive intravenous PCC Receiving heparin with a therapeutic dose INR˃1.5 (PLT˂100000) Thrombocytopenia Patients receiving warfarin Hemochromatosis patients Chronic renal failure (GFR˂40) More than 48 hours have passed since the onset of sepsis

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be recorded on an Excel file by the principal investigator. Participants will be randomized via permuted block randomization. Each block will be consistent of variable sizes of 4 or 6 or 8 patients. For assignment of each patient to the drug or control group, for each patients a unique code consistent of 2 letters and a digit will be assigned. the code will be unique for each patient (for example code AB1 for first patient). Only the principle investigator will be informed of the assignment of each code to the medication or control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are included in the study after obtaining consent, but patients are blinded to whether they receive only the treatment of Titarard or receive it along with the standard treatment of vitamin C.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Vice-Chancellor in Research Affairs- Tehran University of Medical Scien

Street address
Keshavarz Blvd., intersection of Quds St., University of Medical Sciences Central Building, 6th floor, room 604

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2020-04-06, 1399/01/18

Ethics committee reference number
IR.TUMS.VCR.REC.1399.158

Health conditions studied

1

Description of health condition studied
Covid 19

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Antithromobin III

Timepoint
From the beginning to the end of the course

Method of measurement
elisa kit

2

Description
Neutrophil to lymphocyte ratio

Timepoint

From the beginning to the end of the course

Method of measurement

Counting blood cells (CBC diff).

3

Description

syndecan-1

Timepoint

From the beginning to the end of the course

Method of measurement

Kit

4

Description

Mortality

Timepoint

From the beginning to the end of the course

Method of measurement

observation

5

Description

Vasopressor dose

Timepoint

From the beginning to the end of the course

Method of measurement

observation

6

Description

CRP/ALB ratio

Timepoint

From the beginning to the end of the course

Method of measurement

Laboratory

7

Description

ACR

Timepoint

From the beginning to the end of the course

Method of measurement

Laboratory

8

Description

FDP/D-Dimer Ratio

Timepoint

From the beginning to the end of the course

Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Control group: They will receive only standard treatment.

Category

Treatment - Drugs

2

Description

Intervention group: In addition to standard treatment (antibiotics, fluid therapy, etc.), they will receive 25 mg/kg of vitamin C (Vial of injectable vitamin C 500mg/5ml, Alborz Daro) as a bolus every six hours for 72 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Kiumarth Amini

Street address

Imam Khomeini St, Hasan Abad Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Medical Sciences in Tehran

Street address

13th Floor, Block A, Ministry of Health, Medical Education, Simai Street, between South Flamak and Zarafshan, Quds town, Iran

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1417653761

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+98 912 519 7344
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Kiumarth Amini
Position
Resident
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Number 76, Niloufar alley, Abidar st
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

All data can be shared.

When the data will become available and for how long

The access period starts six months after the publication of the article.

To whom data/document is available

All researchers

Under which criteria data/document could be used

for research purposes.

From where data/document is obtainable

In the uploaded databases, the link will be provided to the applicants.

What processes are involved for a request to access data/document

Check the requester's information and then send the link.

Comments