Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The effect of hydrocortisone , vitamin C, and thiamine for treatment of patients with septic shock addmited to intensive care unit of Ayatollah Mousavi hospital in Zanjan , in 2017-18

Protocol summary

Study aim
The effect of hydrocortisone, vitamin C, and thiamine for treatment of patients with septic shock admitted to intensive care unit(ICU) of Ayatollah Mousavi hospital in Zanjan between 2017 and 18

Design
Fifty eight patients with diagnosis of septic shock who admitted to intensive care unit (ICU) were divided into intervention and control group with simple randomization method.

Settings and conduct
In addition to routine sepsis treatment protocol,patients with septic shock admitted to intensive care unit of Ayatollah Mousavi hospital in Zanjan were treated by combination of hydrocortisone ,vitamin C and thiamine for 72 hours in intervention group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with septic shock and equal APACHE II score hospitalized in intensive care unit(ICU) Intubated patients Patients between 18 years and 70 PCT level more than 2 ng/dl Non inclusion criteria: Pregnant patients

Intervention groups
Twentynine patients with diagnosis of septic shock were treated with intravenous combination of Hydrocortisone, vitamin C, Thiamine for seventy two hours and twonty nine patients in control group treated by standard septic shock treatment guideline.

Main outcome variables
1-procalcitonin level change 2-lactate level change 3-leukocyte Count change 4-SOFA Score change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023760N7**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **retrospective**

Last update: **2019-02-22, 1397/12/03**
Update count: **0**

Registration date
2019-02-22, 1397/12/03

Registrant information

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Mohammad Reza Jamshidi
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-29, 1397/03/08

Expected recruitment end date
2018-11-28, 1397/09/07

Actual recruitment start date
2018-05-29, 1397/03/08

Actual recruitment end date
2018-11-30, 1397/09/09

Trial completion date
2019-01-05, 1397/10/15

Scientific title
The effect of hydrocortisone , vitamin C, and thiamine for treatment of patients with septic shock addmited to

intensive care unit of Ayatollah Mousavi hospital in Zanjan , in 2017-18

Public title
The effect of hydrocortisone, vitamin C, and thiamine for treatment of septic shock

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with septic shock and the same Acute Physiology, Age, chronic health evaluation II (APACHE II score) admitted to intensive care unit Intubated patients Age between 18 to 70 years Serum pro-calcitonin level ≥ 2ng/ml.

Exclusion criteria:
Pregnant patients

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **58**
Actual sample size reached: **58**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study patients who met inclusion criteria were divided into intervention and control group by simple randomization method. Fiftyeghit patients with diagnosis of septic shock in critical care unit of ayatollah mousavi hospital after matching for demographic data’s and Apache 2 Score we’re divided into intervention group and control group by randomization with computerized random number tables.This method is one of basic methods for sampling in experimental studies, and frequently is used in studies with a few sample size.For randomization between two groups, random numbers table is used.In this study fiftyeghit patients with diagnosis of septic shock in critical care unit of ayatollah mousavi hospital after matching for demographic data’s and Apache 2 Score we’re divided into intervention group and control group by randomization with computerized random number tables.Fifty eight random numbers were extracted of computer by using random number table and for example 24th sample was set in intervention group and 14th sample was set in control group and this process was performed until end of the study.

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 Zanjan University of Medical Sciences

Street address
Mousavi hospital,Sobotie Blvd, Zanjan

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Zanjan

Province
Zanjan

Postal code
4513956183

Approval date
2018-05-28, 1397/03/07

Ethics committee reference number
IR.ZUMS.REC.1397.041

Health conditions studied

1

Description of health condition studied
Septic shock

ICD-10 code
R65.21

ICD-10 code description
Severe sepsis with septic shock

Primary outcomes

1

Description
The Sequential organ function assessment (SOFA) score:a factor for evaluation of organ function

Timepoint
One day Later-Three days Later

Method of measurement
SOFA table was used to measure the performance of the organs.

2

Description
Serum lactate(a factor for evaluation of Oran perfusion)

Timepoint
One day Later-Three days Later

Method of measurement
Lactate measurement kit was used to measure lactate.

3

Description
WBC count(leukocyte Count as a factor for evaluation of

sepsis progression)

Timepoint

One day Later-Three days Later

Method of measurement

Cell counters were used to measure the number of white blood cells.

4

Description

Need for vasopressors (definition of septic shock is sepsis which requires treatment with vasopressors)

Timepoint

One day later-Three days later

Method of measurement

For measuring the vasopressors, the average pressure is used, the unit is micrograms per minute.

5

Description

Serum procalcitonin (indicator of sepsis severity)

Timepoint

One day later-Three days later

Method of measurement

The measure of procalcitonin was VIDAS B.R.A.M.S PCT assy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group has received the assessed combination therapy, including hydrocortisone (50mg/each 6h, intravenously), vitamin C (1.5g/6h in 100ml DW5%, intravenously), and thiamine (200mg/12h in 50ml DW5%, intravenously)in addition to standard septic shock treatment protocols for seventy two hours.

Category

Treatment - Drugs

2

Description

Control group: This group has treated by standard septic shock treatment protocols including antibiotic therapy, prophylaxis of deep venous thrombosis, sedative medications, mechanical ventilation and prescription of vasopressor without additional intervention .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi hospital

Full name of responsible person

Mohammadreza Jamshidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Mohammadreza Jamshidi

Position
Associate professor

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
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
After the end of study,We will share non-identifiable individual data of the participants, the study protocol, the statistical analysis of the data, the informed consent form patients,clinical reports, analysis codes, and data coding systems (data Dictionary) .

When the data will become available and for how long
We will share our study results in 2019.

To whom data/document is available
The data from this study will be available to all people who can play a role in caring of septic patients, such as families, and healthcare workers.

Under which criteria data/document could be used
The results of this study will be useful for care providers especially involving in septic patients admitted to

intensive care units.

From where data/document is obtainable

To receive information anyone can be use the following email: jamshidianes@zums.ac.ir

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

we will send the results of our study to the applicants .

Comments