

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of hydrocortisone , vitamin C, and thiamine for treatment of patients with septic shock addmitted 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

Name

Mohammad Reza Jamshidi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 334 6346

Email address

jamshidianes@zums.ac.ir

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 addmitted 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 $\geq$ 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. Fiftyeight 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 fiftyeight 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

City

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 Organ 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 assay

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
Street address
Ayatollah Mousavi Hospital, Sobotie Blvd, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
+98 24 3313 0000
Fax
+98 24 3313 1419
Email
jamshidianes@zums.ac.ir
Web page address
<http://www.zums.ac.ir>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza shoghli
Street address
Azadi Blvd, Zanjan
City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24 3322 4766
Fax
+98 24 3322 4766
Email
research@zums.ac.ir
Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=3
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

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

Street address

Mousavy Hospital, Sobotie Blvd, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

jamshidianes@zums.ac.ir

Web page address

http://www.zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohammadreza Jamshidi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Zanjan, Gavazang Ave, Mousavy Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

jamshidianes@zums.ac.ir

Web page address

http://www.zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohammadreza Zeraati

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Critical care medicine

Street address

Ayatollah Mousavy Hospital, Sobotie Blvd, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

mohammadrezazeraati@zums.ac.ir

Web page address

http://www.zums.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

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