

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of Steroids (Hydrocortisone), Thiamine and Ascorbic Acid Supplementation in Septic Shock (STASIS) in hospitalized patients in intensive care unit : A Prospective, triple-blinded, Randomized, Controlled clinical trail

Protocol summary

Study aim

To determine if the addition of hydrocortisone, thiamine and ascorbic acid to standard care versus standard care in septic shock confers an in-hospital and 28-day mortality benefit

Design

A triple blinded, randomized, parallel clinical trial with control group

Settings and conduct

A multi-center (Baqiyatallah, Sina, Shariati, Imam khomeini, and Masih daneshvari hospitals in Tehran and Besat hospital in Hamadan), triple-blinded (Patient, data collector researcher, and statistician), two groups (intervention and control) clinical trial will be conducted by convenience sampling and then, random allocation using four-block in suffering hospitalized patients in medical and surgical (general) intensive care unit from septic shock. In the intervention group, patients will receive three hydrocortisone, thiamine, and ascorbic acid drugs along with routine treatment and the control group will receive routine treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria • Septic shock • Age $\geq$ 18 years
Exclusion Criteria • Age < 18 years • Pregnant • Patients with limitation of care (i.e. do not resuscitate [DNR]) • Known Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency • Excluding primary admission diagnosis including the following: acute stroke; acute coronary syndrome; active gastrointestinal bleed; burn; trauma • Vasopressor use prior to randomization for more than 24 hours

Intervention groups

Intervention group: Receiving three drugs hydrocortisone, thiamine and ascorbic acid along with standard care and Control group: Receiving standard care

Main outcome variables

Primary: 28-day mortality rate Secondary: (1) More rapid improvements in illness severity (2) Greater changes in biochemical profiling (3) Improved hospital stay metrics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160901029640N2**

Registration date: **2019-11-13, 1398/08/22**

Registration timing: **prospective**

Last update: **2019-11-13, 1398/08/22**

Update count: **0**

Registration date

2019-11-13, 1398/08/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 3505

Email address

amirvahedian@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Steroids (Hydrocortisone), Thiamine and Ascorbic Acid Supplementation in Septic Shock (STASIS) in hospitalized patients in intensive care unit : A Prospective, triple-blinded, Randomized, Controlled clinical trail

Public title

Steroids (Hydrocortisone), Thiamine and Ascorbic Acid Supplementation in Septic Shock

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Septic shock patients -as defined by SEPSIS-3- hospitalized in the ICU in the first 24 hours

Exclusion criteria:

Vasopressor use prior to randomization for more than 24 hours Patients with limitation of care (Decision has been made to reduce the level of care)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (groups of 2) will be performed using random numbers list generated by Random Allocation Software © (RAS; Informer Technologies, Inc., Madrid, Spain). The numbers will be placed into sequential containers that will be kept in a secure location until allocation consignment. Enrollment and randomization will be occurred in the emergency department from available admitted ICU patients on a convenience basis. Only patients will be admitted to the ICU through the emergency department will be eligible for inclusion. The consignment will be implemented though: A person who divides patients into control and intervention groups will not be aware of the grouping of individuals.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To ensure blinding, the allocation sequence will be kept by a different investigator than the one enrolling participants. A third investigator will be responsible for patient follow-up and assessments. Patients will not know what group they are in. Nurses, researchers, and data collectors will not be aware of patient grouping. The two intervention and control groups will not be specified for the statistician.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

Clinical trial.gov

Secondary trial Id

NCT04134403

Registration date

2019-09-23, 1398/07/01

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

Street address

Daneshgah-e-Bu Ali Sina, Hamedan, Hamadan Province

City

Hamadan

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Postal code

1434589753

Approval date

2019-10-16, 1398/07/24

Ethics committee reference number

IR.UMSHA.REC.1398.554

Health conditions studied**1****Description of health condition studied**

Sepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

Primary outcomes

1

Description

28-day mortality rate

Timepoint

Up to 28th day of hospitalization in intensive care unit

Method of measurement

Checklist

Secondary outcomes

1

Description

rate of mechanical ventilation support

Timepoint

Daily, Up to 28th day of hospitalization in intensive care unit

Method of measurement

Checklist

2

Description

Duration of Intubation

Timepoint

Daily, Up to 28th day of hospitalization in intensive care unit

Method of measurement

Check list

3

Description

Vasopressor duration

Timepoint

Daily, Up to 28th day of hospitalization in intensive care unit

Method of measurement

Checklist

4

Description

SOFA score rate

Timepoint

Daily, Up to 28th day of hospitalization in intensive care unit

Method of measurement

Checklist

5

Description

Procalcitonin level

Timepoint

Daily, Up to 28th day of hospitalization in intensive care unit

Method of measurement

Immunoluminometric assay by BRAHMS test loam kits in ng / ml

6

Description

CRP level

Timepoint

Daily, Up to 28th day of hospitalization in intensive care unit

Method of measurement

Immunoenzymometric assay by Diagnostic Biochem kit in ng / ml

7

Description

Hospital Length of stay

Timepoint

Daily, after discharge from intensive care unit and until hospitalization

Method of measurement

Hospitalized days Checklist

8

Description

Intensive care unit Length of stay

Timepoint

Daily, Up to 28th day of hospitalization in intensive care unit

Method of measurement

Hospitalized days Checklist

Intervention groups

1

Description

Intervention group: Receiving three drugs hydrocortisone (50 mg, every 6 hours, 7 days or until ICU discharge), thiamine (200 mg, every 12 hours, 4 days or until ICU discharge), Ascorbic acid (1,500 mg, every 6 hours, 4 days or until ICU discharge) + Standard treatment of intensive care unit

Category

Treatment - Drugs

2

Description

Control group: Receiving standard treatment of intensive care unit

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Dr Amir vahedian-azimi

Street address

sheikh bahaei street

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Tehran

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2

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr Farshid Rahimibashar

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Shahid Motahari Boulevard, Resalat Square

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3

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Farshid Rahimibashar

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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

Hamedan University of Medical Sciences

Proportion provided by this source

20

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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr Amir vahedian-azimi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available