Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥ 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
Province
Hamadan
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
City
Tehran
Province
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Postal code
71 9135 1435
Phone
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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
Sina hospital
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5

Recruitment center
Name of recruitment center
Imam Khomeini hospital
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yunespanahi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Farshid Rahimibashar
Street address
Shahid Motahari Boulevard, Resalat Square
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71 9153 1435
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+98 81 3265 1515
Email
fr_rahimibashar@yahoo.com
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

Nursery

Street address

Sheikh Bahaie Street, Vanak Sqaure

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Email

amirvahedian63@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Yunes Panahi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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City

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Postal code

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fr_rahimibashar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Farshid rahimibashar

Position

Associate profeessor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Postal code

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Email

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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