Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating effect of early adminestration of corticosteroid in sepsis; A randomized clinical triali

Protocol summary

Study aim
Evaluating effect of early corticosteroid adminestration in sepsis

Design
TThis is a triple-blind, randomized clinical trial in which 40 eligible patients will be allocated in 1:1 to the intervention or control group according to the permuted block randomization. The study is phase 3.

Settings and conduct
This triple-blind, randomized clinical trail will be organized in Imam Khomeini Hospital Complex. Patients with diagnosis of sepsis in first 24-hour of admission are candidates for evaluation. Eligible patients will be randomly assigned in the control or intervention group using permuted block randomization. Concomitant with the standard of care (fluids, antibiotic, management of electrolytes and acid-base disturbances and metabolic supports) patients in the intervention and control group will receive intravenous hydrocortisone 50 mg every 6-hour or placebo for up to 48 hours respectively. Patient, physician and investigator are blind about type of intervention.

Participants/Inclusion and exclusion criteria
Septic patients between 18 and 89 years old, SOFA SCORE≥2, SBP<90mmHg or plasma lactate level of > 2mmol/L

Intervention groups
Control group: Will receive standard care of sepsis including fluid resuscitation, antimicrobial therapy, correction of electrolytes and acid-base imbalances and metabolic supports along with placebo. Intervention group: Will receive standard care of sepsis including fluid resuscitation, antimicrobial therapy, correction of electrolytes and acid-base imbalances and metabolic supports along with intravenous hydrocortisone 50 mg every 6-hour for up to 48 hours.

Main outcome variables
Time to enter the septic shock

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230701058635N1**
Registration date: **2024-02-16, 1402/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-16, 1402/11/27**
Update count: **0**

Registration date
2024-02-16, 1402/11/27

Registrant information

Name
Ehsan Emami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6670 2171

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e-emami@student.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2025-01-20, 1403/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating effect of early adminestration of corticosteroid in sepsis; A randomized clinical triali

Public title
Effect of early adminestration of corton in sepsis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18–89 years Systolic blood pressure of <90 mmHg or plasma lactate level of >2 mmol/L SOFA score of ≥2 points consequent to the infection
Exclusion criteria:
Rejection of sepsis diagnosis after initial evaluations Decision to limit or withdraw treatment Steroid use within 4 weeks Chemotherapy for underlying malignancy within 4 weeks Etomidate use during hospitalization Pregnancy or lactation Informed written consent cannot be obtained from a patient or legal representative Corticosteroides contraindications
Age
From **18 years** old to **89 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done according to the block randomization method. regarding the sample size, 4 patients will be included in each group. Randomization groups generally are AABB, ABAB, ABBA, BABA, BAAB, and BBAA. Rndom numbers will be generate using Excel sofware.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Intravenous hydrocortisone and saline will be prepared and labelled by a technician who is not involved in the study. As complete solubility of hydrocortisone in saline; without any distinct color and smell, same volume of saline will be labelled as control. Patient, physician an clinical evaluator are not aware regarding syringes contents.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Ghods Ave. Tehran University of Medical Science
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2023-06-28, 1402/04/07
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.046

Health conditions studied

1

Description of health condition studied
sepsis
ICD-10 code
R65.1
ICD-10 code description
Systemic Inflammatory Response Syndrome of infectious origin with organ failureSevere sepsis

Primary outcomes

1

Description
Time to enter the septic shock
Timepoint
Every 1-hour
Method of measurement
According mean artrial pressure

Secondary outcomes

1

Description
Vasopressor requirement
Timepoint
Every 1-hour
Method of measurement
Starting a vasopressor drug (type and dose)

2

Description

Need for mechanical ventilation support
Timepoint
Every 1-hour
Method of measurement
Patient intubation

3

Description
7-day mortality
Timepoint
7 days after initial treatment
Method of measurement
patient follow-up

4

Description
28-day mortality
Timepoint
28 days after initial treatment
Method of measurement
patient follow-up

5

Description
length of stay in ICU
Timepoint
Daily
Method of measurement
patient follow-up

Intervention groups

1

Description
Concomitant with the standard of care (fluid resuscitation, antibiotic therapy, management of electrolytes and acid-base disturbances and metabolic supports) patients will receive intravenous hydrocortisone 50 mg every 6-hour for up to 48 hours.
Category
Prevention

2

Description
Control group: Concomitant with the standard of care (fluid resuscitation, antibiotic therapy, management of electrolytes and acid-base disturbances and metabolic supports) patients will receive 4-ml placebo as intravenous injection every 6-hour for up to 48 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Ehsan Emami
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End of Keshavarz Blvd, Imam Khomeini Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Web page address
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
Ehsan Emami
Position
Student
Latest degree
Medical doctor
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Medical Pharmacy
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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
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
Yes - There is 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
Title and more details about the data/document
Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript
When the data will become available and for how long
One year after finishing the study, data will be published and will be available in databases
To whom data/document is available
After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes
Under which criteria data/document could be used
Other researchers are permitted to included the results in their systematic reviews and metaanalysis
From where data/document is obtainable
For this you may ask from scientific responsible person.
What processes are involved for a request to access data/document
After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor

within 2 weeks	**Comments**