Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Effect of intravenous hydrocortisone in patients with refractory septic shock admitted in Imam Reza hospital

Protocol summary

Summary

The purpose of this study is to determine the effect of intravenous hydrocortisone in patients with refractory septic shock. This is a triple blind, randomized, placebo-controlled, single-center study. There is 80 patients in each group. Patients referred to Imam Reza (AS) hospital who have criteria for septic shock, and did not respond to vasopressor administration for more than 60 minutes are included in this study. After explanation of the study to the patients and their consents, they randomly divide into two groups. A group is treated with hydrocortisone 50 mg every 6 hours, and the other group receive placebo for 7 days. Those who suffer from adrenal insufficiency before admission or have had tuberculosis or had been treated with ketoconazole or estrogen are excluded. The patients who had no consent with this study are also excluded. Then, the response to hydrocortisone and 28-day mortality rate in two groups will be studied. Hydrocortisone respond is defined as no further need to vasopressor. Antibiotics administration time is within 1 hour of initial diagnosis of septic shock in all patients. The initial selection of antibiotics based on valid guidelines available. Continuation of antibiotic therapy will be according to culture results.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080211956N2**
Registration date: **2014-10-19, 1393/07/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-19, 1393/07/27

Registrant information

Name
Morteza Talebi Doluee
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3852 5312
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talebidm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous hydrocortisone in patients with refractory septic shock admitted in Imam Reza hospital

Public title

Effect of intravenous hydrocortisone in patients with septic shock

Purpose

Treatment

Inclusion/Exclusion criteria

All patients above eighteen who admitted in Imam Reza Hospital of Mashad with diagnosis of septic shock and do not respond to vasopressor therapy more than 60 minutes are included. Those who suffer from adrenal insufficiency before admission or had tuberculosis or had

been treated with ketoconazole or estrogens are excluded. Those with no consent with the plan are also excluded

Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of medical sciences
Street address
Ethics committee-Ghoreishi building- Daneshgah Ave.
City
Mashhad
Postal code
9137191-3316
Approval date
2013-11-30, 1392/09/09
Ethics committee reference number
920688

Health conditions studied

1

Description of health condition studied
Septic shock
ICD-10 code
R57.2
ICD-10 code description
Septic shock

Primary outcomes

1

Description
Mortality in 28 days
Timepoint
During 28 days
Method of measurement
Death records

Secondary outcomes

1

Description
Response to vasopressor
Timepoint
The time that there is no need to vasopressor
Method of measurement
Normal central vein pressure (6-12 Cm H2O), mean arterial pressure more than 65 mmHg

Intervention groups

1

Description
Hydrocortisone administration every 6 hours for 7 days in intervention group
Category
Treatment - Drugs

2

Description
Placebo (normal saline solution 0.9%) administration every 6 hours for 7 days in control group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza (AS) hospital
Full name of responsible person
Dr. Morteza Talebi
Street address
Imam Reza (AS) hospital, central office of emergency medicine
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of medical Siences
Full name of responsible person

Vice Chancellor of research, Dr. Mohsen Tafaghodi

Street address

Vice Chancellor of research- Ghoreishi building- Daneshgah Ave

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of medical Siences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Azadeh Mahmoudi Gharaee

Position

MD, resident of emergency medicine

Other areas of specialty/work

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Department of Emergency Medicine, Imam Reza Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Emergency Medicine, Mashhad University of Medical Sciences

Full name of responsible person

Dr Morteza Talebi Deloei

Position

Emergency Medicine specialist, assistant professor of emergency medicine

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of medical Siences

Full name of responsible person

Dr. Morteza Talebi

Position

Assistant professor of emergency medicine, Mashhad University of medical Siences

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty