

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Feb 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)

##### Phone

+98 51 3852 5312

##### Email address

talebids@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 Mashhad 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 Sciences

##### 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 Sciences

**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**

**Street address**

Department of Emergency Medicine, Imam Reza  
Hospital

**City**

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**Postal code**

**Phone**

+98 51 3852 5312

**Fax**

**Email**

mahmoudia913@mums.ac.ir

**Web page address**

**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**

**Street address**

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of medical Sciences

**Full name of responsible person**

Dr. Morteza Talebi

**Position**

Assistant professor of emergency medicine, Mashhad  
University of medical Sciences

**Other areas of specialty/work**

**Street address**

Imam Reza (AS) hospital, central office of emergency  
medicine

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3852 5312

**Fax**

**Email**

talebidm@mums.ac.ir

**Web page address**

**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*