

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Effects of only Ribavirin and Additional Therapy with dexamethasone on clinical outcome Among Patients With severe Crimean-Congo Hemorrhagic Fever

#### Protocol summary

##### Summary

(1) Comparison effect of ribavirin alone and in combination with dexamethasone on clinical outcome of patients with severe form of haemorrhagic Crimean-Congo fever, (2) All patients with severe form of haemorrhagic Crimean-Congo fever C since July 2015 until April 2016 admitted in Boo-Ali infectious diseases hospital-Zahedan, 50 individual in two groups of 25 case, not blinded, block-randomized, single-center, phase 2,(3) The intervention group receive dexamethasone and ribavirin and control group are treated only with ribavirin. Then, mortality, length of hospital stay and the need for blood products used in both groups compared. (4) Inclusion criteria included having at least one criteria of severe form of the disease include severe reduction in platelet count (platelets less than 20,000); signs of bleeding as petechiae, ecchymosis and obvious bleeding; fibrinogen level less than or equal to 120 milligrams per deciliter; partial thromboplastin time more than or equal to 60 seconds; decreased level of consciousness. (5) Ribavirin 30 milligram per killogram for the first dose, then 16 milligram per killogram every 6 hours for 4 days, then 8 milligram per killogram every eight hours for six days as control group and ribavirin as noted in cintrol group in addition to dexamethasone 10 milligram per square meter body. (6) the rate of recovery-death mortality rate and blood products used in both groups recorded and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120525378N1**

Registration date: **2016-05-18, 1395/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-18, 1395/02/29

##### Registrant information

###### Name

Shahab-Aldin Mashaie

###### Name of organization / entity

Zahedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3342 9659

###### Email address

dr.mashaei@zavms.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Zahedan University of Medical sceinces

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2016-04-19, 1395/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of only Ribavirin and Additional Therapy with dexamethasone on clinical outcome Among Patients With severe Crimean-Congo Hemorrhagic Fever

##### Public title

Effects of Ribavirin and dexamethasone on clinical

outcome of Crimean-Congo Hemorrhagic Fever

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: severe thrombocytopenia (plt<20000); petechiae, ecchymosis or bleeding; low serum levels of fibrinogen ( $\leq 120$  mg/dl); ptt $\geq 60$ ; Loss of consciousness

Exclusion criteria: no sever CCHF (base on SSI criteria); pregnancy; underlying disorder; receive

Immunosuppressive drugs; Patients who do not have the necessary cooperation; All patients who received any antiviral , blood or blood products from the onset of symptoms to admission to Boo\_Ali hospital; All patients who have not confirmed CCHF

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan University of Medical sceinces

##### Street address

Ethics Committee of Zahedan Medical University of Science, Zahedan University of Medical sceinces, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

##### City

Zahedan

##### Postal code

#### Approval date

2015-05-03, 1394/02/13

#### Ethics committee reference number

IR.ZAUMS.REC.1394.47

## Health conditions studied

### 1

#### Description of health condition studied

Crimean-Congo Hemorrhagic Fever

#### ICD-10 code

A98.0

#### ICD-10 code description

Central Asian haemorrhagic fever

## Primary outcomes

### 1

#### Description

Mortality rate

#### Timepoint

After intervention

#### Method of measurement

Based on the observed and recorded data

### 2

#### Description

Need of blood products

#### Timepoint

After Intervention

#### Method of measurement

According to transfused units

### 3

#### Description

Recovery rate

#### Timepoint

After intervention

#### Method of measurement

Based on the observed and recorded data

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: ribavirin 30 milligram per kilogram for the first dose then 16 milligram per kilogram every 6 hours for 4 days then 8 milligram per kilogram every eight hours for six days

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: ribavirin 30 milligram per killogram for the first dose, then 16 milligram per killogram every 6 hours for 4 days, then 8 milligram per killogram every

eight hours for six days in addition to dexamethasone 10 milligram per square meter body

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Boo-Ali Hospital of Zahedan

**Full name of responsible person**

Shahab-Aldin Mashaie

**Street address**

Amir-Al-Momenin St., Boo-Ali Hospital, Zahedan

**City**

Zahedan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research,Zahedan University of Medical Sciences

**Full name of responsible person**

Mohsen Taheri

**Street address**

Vice chancellor for research, Zahedan University of Medical Sciences, Hesabi Square, Zahedan

**City**

Zahedan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research,Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Shahab-Aldin Mashaie

**Position**

Infectious disease Residence

**Other areas of specialty/work**

**Street address**

Zahedan University of Medical Sciences, Dr.Hesabi Sq.,Daneshgah Ave., Zahedan

**City**

Zahedan

**Postal code**

**Phone**

+98 54 3341 5705

**Fax**

**Email**

shahabhsm@yahoo.com

**Web page address**

www.zaums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Shahab-Aldin Mashaie

**Position**

Infectious Disease Residence

**Other areas of specialty/work**

**Street address**

Zahedan Medical University of Science, Dr.Hesabi Sq., Daneshgah Ave., Zahedan

**City**

Zahedan

**Postal code**

**Phone**

+98 54 3341 5705

**Fax**

**Email**

dr.mashaei@zaums.ac.ir

**Web page address**

www.zaums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Shahab-Aldin Mashaie

**Position**

Infectious Diseases Residence

**Other areas of specialty/work**

**Street address**

Zahedan Medical University of Science, Dr.Hesabi Sq., Daneshgah Ave., Zahedan

**City**

Zahedan

**Postal code**

**Phone**

+98 54 3341 5705

**Fax**

**Email**

shahabhsm@yahoo.com

**Web page address**  
www.zaums.ac.ir

## 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*