

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 control 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 sciences

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 (≤ 120 mg/dl); ptt ≥ 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

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Person responsible for updating data

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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