Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of Hydrocortisone,Vitamin C and Thiamine in treatment of patients with severe Sepsis/Septic shock in ICU

Protocol summary

Study aim

General purpose: The effect of a combination of hydrocortisone, vitamin C and thiamine in the treatment of patients with septic shock in intensive care units is investigated.

Design

Clinical trial with control group, with parallel, double-blind, randomized phase 2 on 50 patients, patients will be randomly divided into two groups by block method in the form of 4 blocks.

Settings and conduct

All patients with severe septic shock / sepsis admitted to the intensive care unit of Valiasr Hospital in Arak double blind study In this study, patients as well as the project data analyst and the project Intern who is responsible for completing the questionnaires will be unaware of the division of patients into two groups

Participants/Inclusion and exclusion criteria

Study entering criteria: A patient with a diagnosis of septic shock is admitted to the intensive care unit; No covid-19 disease (negative PCR); Age 18 years or above; No pregnancy; No G6PD deficiency disease; No initial diagnosis of:Stroke, Acute Coronary Syndrome, Active Gastrointestinal bleeding, Burns and Trauma; No use vasopressors for more than 24 hours before entering the study Study exiting criteria: Non cooperation

Intervention groups

Patients admitted to the intensive care unit with a diagnosis of severe sepsis / septic shock One group receives a combination of hydrocortisone and vitamin C and thiamine, and the other group receives routine treatment.

Main outcome variables

The duration of intubation, the length of stay in the intensive care unit, the length of stay in the hospital, the length of time the vasopressor is taken and the mortality at the end of 7 days will be recorded in two groups. SOFA score up to 7 days and CRP and lactate levels will be measured on days 1, 3 and 5. The severity of the disease will be measured by the APACHII criterion for up to 3 days.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220219054058N1**
Registration date: **2022-03-01, 1400/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-01, 1400/12/10**
Update count: **0**

Registration date

2022-03-01, 1400/12/10

Registrant information

Name

Mobina Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 4617

Email address

mobinaaahosseini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-04-30, 1401/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Hydrocortisone,Vitamin C and Thiamine in treatment of patients with severe Sepsis/Septic shock in ICU

Public title
The effect of Hydrocortisone,Vitamin C and Thiamine in treatment of patients with severe Sepsis/Septic shock

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
NO covid 19 Disease(PCR negative) Age 18or higher No pregnancy No G6PD deficiency No initial diagnosis of: Stroke, Acute Coronary syndrome, Active Gastrointestinal bleeding, Burns and Trauma No use of vasopressors more than 24 hours before entering the study

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

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

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the double-blind study, in this study, patients as well as the project data analyst and the project partner intern who is responsible for completing the questionnaires will be unaware of the division of patients into two groups.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Valiasr hospital,Valiasr square,Khorram street

City
Arak

Province
Markazi

Postal code
3814957558

Approval date
2022-02-22, 1400/12/03

Ethics committee reference number
IR.ARAKMU.REC.1400.319

Health conditions studied

1

Description of health condition studied
septic shock,severe sepsis

ICD-10 code
R65.21

ICD-10 code description
Severe sepsis with septic shock

Primary outcomes

1

Description
Mortality rate, Duration of intubation, Duration of stay in the intensive care unit, Duration of vasopressor, CRP, Lactate, Severity of illness

Timepoint
Mortality at the end of 7 days, Intubation period up to 7 days, Mean daily disease intensity up to 3 days, Mean CRP level on the first, third and fifth day, Duration of stay in intensive care unit up to 7 days, Duration of hospital stay, Mean level Lactate on the first, third and fifth day, Duration of receiving vasopressor up to 7 days

Method of measurement
Questionnaire filled out by Intern

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group receive combined three drugs of Hydrocortisone (50 mg every 6 hours intravenously - Jaber Bin Hayan Pharmaceutical Company, Iran), Thiamine (200 mg in 50 ml of normal saline every 12 hours intravenously - Pouyan daroo ,

Iran), Vitamin C (1500 mg every 6 hours in 100 ml of normal saline intravenously - Osweh Pharmaceutical Company, Iran) for three days in addition to standard treatment in the Intensive care unit.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group receive only standard treatment in the Intensive care unit.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Mobina Hosseini

Street address

Valiasr hospital, Valiasr square, Khorram street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Arak university of medical science, Sardasht

City

Arak

Province

Markazi

Postal code

3848170002

Phone

+98 86 3417 3501

Email

info@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mobina Hosseini

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

postal code 3813138483, Mahdiyar alley, Shariati street, Arak, Iran

City

Arak

Province

Markazi

Postal code

3813138483

Phone

+98 86 3222 4617

Fax

Email

Mobinaaahosseini@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
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Mobinaaahosseini@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available