

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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 of 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 APACHE II 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 18 or 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**

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**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

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**Email**

Mobinaaahosseini@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

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**Province**

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**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