

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effectiveness of initial administration of thiamine in patients with septic shock in patients admitted in the adult intensive care unit

Protocol summary

Study aim

Effectiveness of initial administration of thiamine in patients with septic shock in patients admitted in the adult intensive care unit

Design

Clinical trial with control group, parallel group, Double blinded, randomized controlled trial

Settings and conduct

Patients over 18 years old hospitalized in Intensive Care Unit of Emam Reza Hospital in Mashhad that diagnosed with septic shock, 70 cases will be enrolled in the study. blood samples are collected before administration of the study drug and 24 hours after drug administration. candidates randomly are classified into two groups: the septic shock group receiving thiamine (the case group) and septic shock patients not receiving thiamine(the control group). We will give those selected as the intervention group thiamine 200 mgr twice daily for 7 days per oral and in the control group we will give placebo daily.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with septic shock(sepsis and fluid therapy resistant hypotension and lactate level greater than 2 mmol/lit) , greater than 18 years old
Exclusion criteria: hepatic impairment , recent supplement to thiamine,Indication of receiving thiamine ,other causes of increased lactate level.prescribe high-level lactate -related drugs ,CO or Cyanide poisoning,known mitochondrial disease,known or suspected ischemia of the intestine or other organs

Intervention groups

Prescription of Thiamine 200 mg twice daily for 7 days for case group and placebo in the same shape of Thiamine tablets to control group

Main outcome variables

Mortality within 28 days after hospitalization ,duration of hospitalization, lactate level in 0 and 24 hours after the intervention,thiamine level in 0 hour,severity of disease by information on the Acute physiology and chronic health

evaluation (APACHE II) questionnaire and Sequential organ failure assessment (SOFA) questionnaire .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190602043787N2**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Zahra Ataee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

ataeez@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of initial administration of thiamine in patients with septic shock in patients admitted in the adult intensive care unit

Public title

Effect of vitamin B1 on septic shock patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages over 18 years old Patients with septic shock (a patient that meets the criteria for sepsis and despite adequate fluid therapy needs vasopressor to preserve MAP \geq 65 mmHg and serum lactate is greater than 2 mmol) Complete informed consent form in the first stage of legal guardianship and in case of failure we refer to the judge of the country Serum lactate is greater than 2 mmol/Li Hypotension (systolic BP less than 90 mmHg despite adequate fluid therapy needs vasopressor (Dopamine \geq 5 mcg/kg/min or Phenylephrine) Refusal to participate in any other intervention research project

Exclusion criteria:

Liver failure or dysfunction (AST OR ALT $>$ 240 unit/Li or known cirrhosis) based on previous findings that patients with liver dysfunction may have increased levels of thiamine. Indication of receiving thiamine (Alcohol abuse) Other causes of increased lactate levels (seizure in 3 hours) Prescription of high-level lactate-like drugs (Linezolid-Methformin) by your physician Cyanide or CO poisoning Known mitochondrial disease Known or suspected ischemia of the intestine or other organs

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyst

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **3**

Blood samples collect from patient before administration of the study drug (to measure Thiamine and Lactate) as well as 24 hours after administration of the drug (to measure Lactate).

Randomization (investigator's opinion)

Randomized

Randomization description

randomization with quadruple blocks with individual units is used. it is randomization tool with opaque and sealed envelopes. permuted block randomization with quadruple

blocks are used to create randomization according to the sample size which is 70 people, 20 blocks will be produced using the site www.sealedenvelope.com. hidden allocation is using opaque and sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, researchers, healthcare providers (Physicians, nurses, etc.), data collectors, data analyzer and those who evaluate the outcome, are blinded to the treatment prescribed. For the control group, placebo was prescribed which was similar in shape and color and size of the drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Quraish building of MUMS, Daneshgah St, Mashhad, Iran Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2020-02-01, 1398/11/12

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.805

Health conditions studied**1****Description of health condition studied**

Septic shock

ICD-10 code

R65.21

ICD-10 code description

Severe sepsis with septic shock

Primary outcomes**1****Description**

Mortality within hospitalization

Timepoint

28-day hospital mortality rate

Method of measurement

Patient mortality rate

2

Description

Duration of hospitalization in Intensive Care Unit

Timepoint

From the beginning to the end of admission in Intensive Care Unit

Method of measurement

Number of days

3

Description

Level of serum lactate

Timepoint

At 0 and 24 hours after intervention

Method of measurement

By examining blood plasma by the method of autoanalyzer

4

Description

Illness severity

Timepoint

Information on the Acute physiology and chronic health evaluation (APACHE II) questionnaire is collected once a week and Sequential organ failure assessment (SOFA) questionnaire is collected every other day.

Method of measurement

By index Sequential organ failure assessment (SOFA) and Acute physiology and chronic health evaluation (APACHE II) questionnaire.

5

Description

Level of serum thiamine

Timepoint

At 0 hours after intervention

Method of measurement

High-performance liquid Chromatography (HPLC) with normal reference range 16-48 ng/ml

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: These patients are given two 100 milligram Vitamin B1 pills that each contains 100 milligram Vitamin B1 and manufactured by Daroopaksh/iran, twice daily for 7 days per oral.

Category

Treatment - Drugs

2

Description

Control group: in the control group we will give placebo tablet twice daily for 7 days per oral. the placebo will be similar in color, taste, shape and administration to the intervention group, not just the therapeutic effect.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Zahra Ataei

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Avesina Ave, Emam Reza hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Ataee

Position

MD, Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Zahra Ataee

Position

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Latest degree

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

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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