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 hypotention and lactate level greater than 2 mmol/lit) , grater 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 cronic 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

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Iran (Islamic Republic of)

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+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 B1on septic shock patiens

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 adequite fluid thrapy needs vasopressor to preserve MAP ≥ 65mmhg 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 Hypotention(systolic BP less than 90 mmhg despite adequite fluid thrapy needs vasopressor(Dopamin ≥ 5mcg/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-levev lactate -like drugs (Linezolid-Methformine)by your phicision 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 analyser

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 Thimine 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 bilding of MUMS, daneshghah 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 begining to the end of admition 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 euthoanalyzer

4

Description

Illness severity

Timepoint

Information on the Acute physiology and cronic 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 cronic health evaluation (APACHE II) questionnaire.

5

Description

Level of serum thiamine

Timepoint

At 0 hours after intervention

Method of measurement

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: These patients are given two 100 miligram Vitamin B1 pills that each contains 100 miligram Vitamin B1 and manufactured by Daroopakhsh/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 Ataee

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Sponsors / Funding sources

1

Sponsor

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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
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Position
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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