

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Assessing the effect of vitamin B1 and vitamin C on attenuation of mortality due to sever sepsis

Protocol summary

Study aim

Assessing the effect of vitamin B1 and vitamin C on attenuation of mortality due to sever sepsis

Design

during this controlled clinical trial that as block randomization and in phase 3 will perform on 86 patients, 43 patients with sever sepsis that will receive vitamin B1 and vitamin C during 4 days in addition to routine treatment and 43 patients with sever sepsis that will receive only routine treatment including antibiotic, would be compared with together. spss software is used for randomization.

Settings and conduct

in this randomized clinical trial without blinding, all patients with sever sepsis including two study groups in alzahra hospital (Isfahan,Iran) will receive similar antibiotic as routine treatment including intervention group (n=43) that will receive vitamin B1 and vitamin C and control group(n=43) that will not receive these vitamins.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1. presence of sever sepsis based on the diagnosis of expert of infectious diseases. 2. the age up 18 years. 3. ability of patient or his/her in giving consciousness consent exclusion criteria: 1. ability of freely refusal from study. 2. allergic reaction to vitamin B1 and vitamin C

Intervention groups

1. intervention group includes patients with sever sepsis that revive antibiotic concomitant with B1 and C vitamins. 2. comparison group includes patients with sever sepsis that only revive antibiotic.

Main outcome variables

death, duration of hospitalization, CRP level,procalcitonin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210518051339N1**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **prospective**

Last update: **2021-06-01, 1400/03/11**

Update count: **0**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

yasaman eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

yasamaneskandari1400@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of vitamin B1 and vitamin C on attenuation of mortality due to sever sepsis

Public title

Assessing the effect of vitamin B1 and vitamin C on treatment of sever sepsis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

presence of sever sepsis based on the diagnosis of expert doctor of infectious diseases the age up of 18 the patient or his accompany can give Informed consent

Exclusion criteria:

allergic reaction to vitamin B1 and vitamin C patients can exit from study with their tendency

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is designed to randomize subjects into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. spss software will used for randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jerib street, Isfahan,Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2020-02-11, 1398/11/22

Ethics committee reference number

IR.MUI.MED.REC.1399.540

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

sepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

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

measure of mortality

Timepoint

4 days after beginning of consumption of B1 and C vitamines

Method of measurement

report of doctor

Secondary outcomes**1****Description**

recovery

Timepoint

4 days after consumption of B1 and C vitamines

Method of measurement

report of doctor

2**Description**

duration of hospitalization

Timepoint

4 days after consumption of B1 and C vitamines

Method of measurement

report of doctor

Intervention groups**1****Description**

Intervention group: Intervention group: for each patient vitamin B1 pill (600 mg) after 12 hour at each day and vitamin C ampoule (50 mg/kg) one time at each day for 96 hours. duration of therapy for each patient is 4 days. B1 vitamin from Tehran chemistry factory and vitamin C ampoule from daroopakhsh factory will used.

Category

Treatment - Drugs

2

Description

Control group: 43 patients in control group will receive only antibiotic drug as routine treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

alzahra hospital

Full name of responsible person

dr. kiana shirani

Street address

sofeh bulvard

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8174673461

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr.kiana shirani

Position

professor

Latest degree

Specialist

Other areas of specialty/work

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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