Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Isfehan
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
City
isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8597
Email
kianashirani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
dr.kiana shirani
Street address
hezar jerib
City
isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
dean@med.mui.ac.ir
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
Infectious diseases
Street address
hezar jerib
City
isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8597
Email
kianashirani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
dr.yasaman eskandari
Position
general medicine
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
hezar jerib
City
isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
y_e522000@ yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
dr.yasaman eskandari

Position
general medicine

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
hezar jerib

City
isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0048

Email
y_e522000@ yahoo.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