Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of the Nutrition Bio-Shield (NBS) herbal supplement on the treatment of patients with nosocomial multi-drug resistant bloodstream infections admitted to emergency Intensive care unit.

Protocol summary

Study aim
Determining the effect of NBS herbal supplement on the treatment of multi-drug resistant nosocomial bloodstream infections in patients referred to the emergency care unit.

Design
A parallel groups, double-blinded, randomized, and phase 3 clinical trial on 94 patients. RAND function of Excel software was used for randomization.

Settings and conduct
In the present study, patients, researchers, nurses and statisticians do not aware about the patients grouping who receive NBS powder. This clinical trial will be conducted at Imam Khomeini Hospital in Tehran. Patients in the intervention group (n=47), in addition to receiving the routine treatment adopted by the attending physician based on the guidelines, will also receive NBS powder for 14 days. The control group (n=47) also received the same treatment panel along with placebo for 14 days. Before and after the intervention, the demographic and laboratory parameters considered in this study are collected from the patients and recorded in the file. Finally, the results will be analyzed by statistical methods.

Participants/Inclusion and exclusion criteria
In this study, patients over 18 years old, whose bloodstream infections has been confirmed by a specialist with clinical symptoms and laboratory parameters, are included in the study. On the other hand, suffering from chronic and autoimmune diseases as well as the use of immunosuppressive drugs by patients are the main criteria for excluding them from the study.

Intervention groups
The intervention group will be prescribed 5.4 grams of NBS powder daily in three doses of 1.5 grams for 14 days along with the main treatment panel. The control group will also receive a placebo in addition to the main treatment panel.

Main outcome variables
Mortality rate; white blood cells counts; hospitalization period

General information

Reason for update

Acronym
NBS-BSI

IRCT registration information
IRCT registration number: **IRCT20230116057135N3**
Registration date: **2023-06-10, 1402/03/20**
Registration timing: **prospective**

Last update: **2023-06-10, 1402/03/20**
Update count: **0**

Registration date
2023-06-10, 1402/03/20

Registrant information

Name
Mehrdad Mosadegh

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01
Expected recruitment end date
2023-10-23, 1402/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of the Nutrition Bio-Shield (NBS) herbal supplement on the treatment of patients with nosocomial multi-drug resistant bloodstream infections admitted to emergency Intensive care unit.

Public title
Effect of the NBS on the treatment of nosocomial infections
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of the occurrence of sepsis in patients with the initial assessment of the patient's clinical symptoms and laboratory parameters Patients over 18 years old Primary diagnosis of sepsis (have at least two of the following four symptoms: hypothermia or hyperthermia, tachycardia, tachypnea, and leukocytosis or leukopenia) by an infectious specialist or a positive MDR culture
Exclusion criteria:
History of consuming corticosteroids and immunosuppressive drugs Pregnant and lactating mothers
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into intervention and control groups by random block method. Allocation of the samples to two groups with random permutation block design will be two treatments with blocks of four. In this way, the letter A is considered for the intervention group and the letter B is considered for the control group. Then we write all the alternating combinations of the letters A, A, B and B, which are 6 different combinations, on 6 cards in this order: AABB, ABBA, ABAB, BAAB, BABA, BBAA, then one digit from 1 to 6, we choose randomness and continue this process until the sample size reaches the quorum.
Blinding (investigator's opinion)
Double blinded
Blinding description
The evaluator and statistician, nurses and patients are blind. In this study, due to examining the process of clinical changes of the patient after taking the NBS herbal supplement and preventing any possible clinical problems in the patients, the doctor is aware of the presence of each patient in each group of the present study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Khomeini Hospital Complex; Tehran University of Medical Sciences
Street address
Imam Khomeini Hospital Complex, Qarib St., Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2023-03-15, 1401/12/24
Ethics committee reference number
IR.TUMS.IKHC.REC.1401.447

Health conditions studied

1

Description of health condition studied
Hospital-acquired bloodstream infections
ICD-10 code
A49.9
ICD-10 code description
Bacterial infection, unspecified

Primary outcomes

1

Description
Measurement of inflammatory factors
Timepoint
Measurement at the beginning of the study (before the

start of the intervention) and 14 days after the start of NBS powder consumption.

Method of measurement

Gold standard methods (ESR measurement by Westergren method, CRP measurement by Electrochemical Immunoassay method)

2

Description

Measurement of white blood cells

Timepoint

Measurement at the beginning of the study (before the start of the intervention) and 14 days after the start of NBS powder consumption

Method of measurement

Cell Counter

Secondary outcomes

1

Description

Mortality Rate

Timepoint

After completing the intervention

Method of measurement

Checking the patient's clinical symptoms

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to the standard treatment panel, receive Nutrition Bio-Shield (NBS) powder as follows: the amount of NBS 500 mg capsule is 4.5 g daily in three doses: 1.5 g in the morning, 1.5 g in the afternoon, and 1.5 g The night is for 14 days.

Category

Treatment - Drugs

2

Description

Control group: In addition to the standard treatment regimen, patients in the control group also receive placebo capsules that are given in the morning, noon, and night.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Arezoo Rasti

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Imam Khomeini Hospital Complex, Keshavarz Blvd., Qarib Street, Tehran

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Research Committee, Faculty of Nursing, Tehran University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mehrdad Mosadegh

Position
Consultant

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

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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