

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of NBS herbal powder effects as a complementary medicine on the recovery of patients with multi-drug resistant tuberculosis

Protocol summary

Study aim

Evaluation of Nutrition Bio-Shield (NBS) herbal supplement effects on the recovery of patients with multi-drug resistant tuberculosis

Design

A controlled, parallel-group, double-blind, by random block method, phase 3 clinical trial on 88 patients.

Settings and conduct

In this study patients and researchers don't know which group of patients will use the Nutrition Bio-Shield (NBS). This clinical trial will be conducted in Imam Khomeini Hospital in Tehran. The intervention group (n=44), in addition to receiving the routine antibiotic panel adopted by the attending physician based on the guidelines, will also receive NBS powder for 6 months. The control group (n=44) also receives the same antibiotic panel along with placebo. 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, our data will be analyzed by significant statistical methods.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with multi-drug resistant tuberculosis ; Patients over 18 years old
Exclusion criteria: Patient's refusal to continue the study ; Patients suffering from any other chronic disease such as diabetes, cardiovascular disease, etc. ; Pregnant and lactating mothers ; Use of corticosteroids and immunosuppressive drugs ; Observing any drug sensitivity as diagnosed by the attending physician ; Patient's death

Intervention groups

NBS (Nutrition Bio-Shield) powder will be prescribed to the intervention group, 4.5 grams daily in three doses of 1.5 grams for 6 months along with antibiotic treatment. In addition to the antibiotic panel, the control group will also receive a placebo.

Main outcome variables

Age ; Sex ; Duration of infection ; Microbial load ; Death ;

Count of white blood cells ; CRP ; ESR ; Hospitalization period

General information

Reason for update

Acronym

NBS-TB

IRCT registration information

IRCT registration number: **IRCT20230116057135N1**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**

Update count: **0**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Mehrdad Mosadegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 935 563 3390

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of NBS herbal powder effects as a complementary medicine on the recovery of patients with multi-drug resistant tuberculosis

Public title
The effect of NBS powder in treatment of patients with multi-drug resistant tuberculosis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with multi-drug resistant tuberculosis Patients over 18 years old
Exclusion criteria:
The patient's withdrawal from the study Patients with any other chronic disease such as diabetes, cardiovascular disease, etc. Patients who have received supplements of vitamin D, zinc, B vitamins and other micronutrients in the last month. Patients who do not come for follow-up treatment at specified intervals Pregnant and lactating mothers Use of corticosteroids and immunosuppressive drugs Observing any drug sensitivity (especially digestive sensitivity to gluten) as determined by the attending physician Deterioration of the patient's clinical symptoms due to the consumption of Nutrition Bio-Shield (NBS) powder, as determined by the attending physician Patient's death during common and selective treatments (in case of death, the patient's information is fully recorded and laboratory tests are performed along with other samples to determine the possible effect of the drug on the patient's death)

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **88**

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 a digit is randomly selected from 1 to 6. and continue this

process until the sample volume reaches the quorum.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study patients and researchers don't know which group of patients will use the Nutrition Bio-Shield (NBS). Physician and clinicians team know about the group who use the powder.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Poursina St., Qods St., Enghelab St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151

Approval date
2023-01-01, 1401/10/11

Ethics committee reference number
IR.TUMS.SPH.REC.1401.206

Health conditions studied

1

Description of health condition studied
Respiratory tuberculosis

ICD-10 code
A15

ICD-10 code description
Respiratory tuberculosis

Primary outcomes

1

Description
Microbial load

Timepoint
Before of the intervention, monthly monitoring, after of the intervention

Method of measurement
Examining the Ziehl-Neelsen staining slide, colony count

2

Description

Measurement of white blood cells

Timepoint

Before of the intervention, After of the intervention

Method of measurement

Cell Counter

3

Description

Measurement of inflammatory factors

Timepoint

Before of the intervention, After of the intervention

Method of measurement

Gold Standard Methods (Westergren method for ESR,
Electrochemical Immunoassay for CRP)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in intervention group in addition to the standard antibiotic treatment regimen + Nutrition Bio-Shield (NBS) powder will be prescribe is below: Dosage of NBS is 500 mg capsules daily in 4.5 grams given in divided doses of 1.5 gram in the morning, 1.5 gram in the noon and 1.5 gram in the night for 6 months.

Category

Treatment - Drugs

2

Description

Control group: Patients in intervention group in addition to the standard antibiotic treatment regimen + Placebo capsules given in the morning, noon and night.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Tehran

Full name of responsible person

Sara Ghaderkhani

Street address

Imam Khomeini hospital, Qarib St., Keshavarz St.,
Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

۱۴۰۱-۳-۱۰۲-۵۸۲۰۱

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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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