Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
m-mosadegh@razi.tums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 8873 6119
Email
m-mosadegh@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Yousef Erfani
Street address
Shafiei St., Qods St., Enghelab St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۷۸۶۴۵۱۳
Phone
+98 912 424 5978
Email
Yerfani@tums.ac.ir
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
Street address

Shafiei St., Qods St., Enghelab St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۱۷۸۶۴۵۱۳

Phone
+98 935 563 3390

Fax

Email
m-mosadegh@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Yousef Erfani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

Street address
Shafiei St., Qods St., Enghelab St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۱۷۸۶۴۵۱۳

Phone
+98 912 424 5978

Fax

Email
yerfani@tums.ac.ir

Person responsible for updating data

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

Street address
Shafiei St., Qods St., Enghelab St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۱۷۸۶۴۵۱۳

Phone
+98 935 563 3390

Fax

Email
m-mosadegh@razi.tums.ac.ir

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