

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing Green Tea and Placebo on Blood iron indices, Sputum Smear Conversion and Expression of Hepcidin and Transferrin receptor Genes in Smear Positive TB Patients

Protocol summary

Summary

This study aims to determine the effects of green tea on the treatment course of smear positive tuberculosis patients. Inclusion criteria include: age older than 16 years with definitive TB diagnosis, not affecting by hepatitis or diabetes mellitus type 1, and exclusion criteria include: severe changes in liver function tests, any autoimmune diseases and allergy to green tea. After acquiring sufficient information and signing informed consent, 88 patients with smear positive TB in the Golestan province will be randomly assigned to intervention and control groups in a double-blinded manner. Besides treatment with antibiotics, the intervention group will receive supplementation with daily green tea capsules contains 400 mg catechins and control group with placebo for 2 months. Demographic data, Food Frequency Questionnaires and anthropometric measurements will perform for patients before and after intervention. Clinical examination at baseline study and follow-up visits (1st & 2nd month) will be done. Food recall will be completed in the 3 inconsecutive days each month. Hemoglobin, TIBC, Ferritin, Transferrin, serum iron, serum malondialdehyde measurement will be done before and after intervention. From third to the ninth weeks every 10 days sputum smear samples will be examined for bacterial load. Cellular mRNA using standard protocol will be purified from biological samples and Transferrin receptor and Hepcidin expression at the transcriptional level will be measured semi-quantitatively. Comparing two groups before and after, statistical analysis will be performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212232602N11**

Registration date: **2013-04-07, 1392/01/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-07, 1392/01/18

Registrant information

Name

Shahryar Eghtesadi

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Council of Golestan University of Medical Sciences
Research Council of Tehran University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-10-21, 1392/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Green Tea and Placebo on Blood iron indices, Sputum Smear Conversion and Expression of Hcpidin and Transferrin receptor Genes in Smear Positive TB Patients

Public title

Clinical and laboratory study on the effects of green tea on the treatment of patients with Smear positive TB

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Definitive diagnosis of TB according to Ministry of Health criteria; Location in Golestan Province ; treatment of patients under DOTS strategy; Age 15 years and over; Willingness to cooperate in study Exclusion criteria : Allergic symptoms or side effects of green tea consumption; Severe changes in liver function tests due to anti-TB drugs; Side-effects of anti-TB drugs

Age

From **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Golestan University of Medical Sciences, Deputy of Research and Technology

Street address

Shast Cola Road, Falsafi Estate

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Postal code

4934174515

Approval date

2012-09-02, 1391/06/12

Ethics committee reference number

G P/ 132414/35

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

Respiratory Tuberculosis

ICD-10 code

A15.0

ICD-10 code description

Tuberculosis of lung, confirmed by sputum microscopy with or without culture

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

sputum smear conversion

Timepoint

from day 20 to 60 every 10 days

Method of measurement

microscopic smear of sputum

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

Hemoglobin

Timepoint

begining of treatment and end of second month

Method of measurement

laboratory measurement

2**Description**

Transferrin receptor gene expression

Timepoint

begining of treatment and end of second month

Method of measurement

real time PCR

3**Description**

Hcpidin gene expression

Timepoint

begining of treatment and end of second month

Method of measurement

real time PCR

4**Description**

TIBC

Timepoint

begining of treatment and end of second month

Method of measurement

laboratory measurement

5

Description

Transferrin

Timepoint

begining of treatment and end of second month

Method of measurement

laboratory measurement

6

Description

Ferritin

Timepoint

begining of treatment and end of second month

Method of measurement

laboratory measurement

Intervention groups

1

Description

The control group will receive placebo capsules for two months daily beside the anti-tuberculosis therapy.

Category

Other

2

Description

The intervention group will receive green tea capsules 400 mg daily beside the anti-tuberculosis therapy.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Province Health Center

Full name of responsible person

Mohammad Reza Honarvar

Street address

Golestan Medical University, Research Council, Shast Cola Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Golestan University of Medical Sciences

Full name of responsible person

Mohammad Jafar Gotalipoor

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Gorgan Golestan Medical University shast cola

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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

Research Council of Golestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Position

PhD student

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*