

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Effect of silymarin in prevention of adverse effects of anti tuberculosis drugs

#### Protocol summary

##### Summary

**Aim:** Decreasing incidence of drug induced hepatitis  
**Study Design:** Double blind, randomized clinical trial with placebo, single center  
**Inclusion criteria:** New cases of pulmonary or extra pulmonary tuberculosis  
**Exclusion criteria:** HIV, HCV or HBV infection, abnormal liver function tests, drug regimen without Isoniazid, Rifampin or Pirazinamide, dissatisfaction of the patient and pregnancy or lactation. Number of cases: 30 cases in every group  
**Method:** In the base we check liver function tests and serology of HIV, HCV and HBV. Then randomly Silymarin 420 mg per day (Livergol 140 three times a day) and placebo prescribe, for the first 2 weeks of anti-tuberculosis treatment, as oral tablets. In this period we will check liver function tests three times weekly and evaluate the patients for nausea, vomiting, anorexia, icter, diarrhea, bloating, itching and skin rash daily. If drug induced hepatitis (Increment in LFT more than 5 times without clinical signs or 3 times with signs) occurs, drug or placebo will be stopped. Drug induced hepatitis will be managed by related physician. Clinical signs and levels of LFT will record in questionnaire and by statistical program  
**Incidence of drug induced hepatitis and probable adverse effects will be compared in two groups.**

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903294209N1**  
Registration date: **2010-08-23, 1389/06/01**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-08-23, 1389/06/01

#### Registrant information

##### Name

Majid Marjani

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences /  
National Institute of Tuberculosis and Lung Disease

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2610 9590

##### Email address

marjani@nritld.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

National research institute of tuberculosis and lung disease

#### Expected recruitment start date

2010-08-23, 1389/06/01

#### Expected recruitment end date

2010-11-21, 1389/08/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of silymarin in prevention of adverse effects of anti tuberculosis drugs

#### Public title

Effect of silymarin in prevention of adverse effects of anti tuberculosis drugs

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: 1- New cases of pulmonary or extra pulmonary tuberculosis 2- Older than 18 years old

Exclusion criteria: 1- HIV infection 2- HCV or HBV infection 3- Abnormal liver function tests at admission 4- Drug regimen without Isoniazid, Rifampin or Pirazinamide 5- Dissatisfaction of the patient 6- Pregnancy and lactation

#### Age

From **18 years** old to **100 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

Australian New Zealand Clinical Trials Registry (ANZCTR)

#### Secondary trial Id

ACTRN12610000621011

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

National research institute of tuberculosis and lung disease

##### Street address

Masih daneshvari Hospital, Dar Abad, Niavaran.

##### City

Tehran

##### Postal code

#### Approval date

empty

#### Ethics committee reference number

p/25/29/50438

## Health conditions studied

### 1

#### Description of health condition studied

Drug induced hepatitis by anti tuberculosis

#### ICD-10 code

Y41.1

#### ICD-10 code description

Antimycobacterial drugs

## Primary outcomes

### 1

#### Description

Drug induced hepatitis

#### Timepoint

three times weekly

#### Method of measurement

Blood levels of liver function tests

## Secondary outcomes

### 1

#### Description

Adverse effects of Silymarin

#### Timepoint

Daily

#### Method of measurement

Daily visit

## Intervention groups

### 1

#### Description

Lactose 420 mg daily in three doses for two weeks as control

#### Category

Placebo

### 2

#### Description

Silymarin 420mg daily in three doses for two weeks as intervention

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Massih Daneshvari Hospital

##### Full name of responsible person

Majid Marjani

##### Street address

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

National Institute of tuberculosis and lung disease

**Full name of responsible person**

Ali Akbar Velayati

**Street address**

Masih daneshvari Hospital, Dar Abad, Niavaran.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

National Institute of tuberculosis and lung disease

**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**

National research institute of tuberculosis and lung disease

**Full name of responsible person**

Majid Marjani

**Position**

Associate professor

**Other areas of specialty/work**

**Street address**

Masih daneshvari Hospital, Dar Abad, Niavaran.

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+98 21 2610 9590

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marjani@nritld.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

National Institute of Tuberculosis and Lung Disease

**Full name of responsible person**

Majid Marjani

**Position**

Infectionist

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

National research institute of tuberculosis and lung disease

**Full name of responsible person**

Majid Marjani

**Position**

Associate professor

**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*