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, anorhexia, icter, diarhea,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) occures, drug or placebo will be stoped. Drug induced hepatitis will be managed by related physician. clical signs and levels of LFT will record in questionaire 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 Unversity 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 lun disease
Full name of responsible person
Majid Marjani
Position
Associate professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Name of organization / entity
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Person responsible for updating data

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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