

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of N-Acetyl cystein in prevention of drug induced hepatitis in tuberculosis patient

Protocol summary

Summary

The main objective of this study is performance measurement of N - acetylcysteine in prevention of liver toxicity due to anti-TB drugs. The population of study are 60 patients receiving anti-tuberculosis drugs that randomly divided into two groups of 30. During the duration of treatment with anti-tuberculosis drugs, the intervention group, are receiving of acetylcysteine 600 mg orally twice daily for a month and control groups, placebo, 600 mg orally twice per day. Demographic data, primary diagnosis, associated diseases and other medications patients are registered. Blood samples at baseline (before starting anti-TB drugs) and then weekly during the first month of the treatment with anti-TB drugs. Test for liver function (liver enzymes and, if necessary, bilirubin), ESR, CRP is measured. Also using the General Health Assessment Questionnaire (28GHQ) the status of general health in the two groups before and at the end of the first month will be compared. Inclusion criteria: age over 50 years; hemodynamic stability (mean arterial blood pressure >70 mmHg or systolic blood pressure >90mmHg) Exclusion criteria: history of acute or chronic renal and liver failure accordance with the definitions of relevant, Unavailability of information related to liver function in basic mode, use of N-acetylcysteine orally, injected or inhaled during 1 month before the beginning of the study; Experience has confirmed that the incidence of hypersensitivity reactions following oral, intravenous or inhaled N-acetylcysteine; receiving concomitant drugs or compounds with antioxidant effects such as vitamin C, vitamin E; HIV + patients; use of alcohol

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205259855N1**

Registration date: **2012-09-08, 1391/06/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-08, 1391/06/18

Registrant information

Name

Aiasghar Farazi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1278 6526

Email address

dr.farazi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2012-09-05, 1391/06/15

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of N-Acetyl cystein in prevention of drug induced hepatitis in tuberculosis patient

Public title

use of acetyl cystein in prevention of anti-TB drug

induced hepatitis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: age over 50 years; hemodynamic stability (mean arterial blood pressure >70 mmHg or systolic blood pressure >90mmHg) Exclusion criteria: history of acute or chronic renal and liver failure accordance with the definitions of relevant, Unavailability of information related to liver function in basic mode, use of N- acetylcysteine orally, injected or inhaled during 1 month before the beginning of the study; Experience has confirmed that the incidence of hypersensitivity reactions following oral, intravenous or inhaled N- acetylcysteine; receiving concomitant drugs or compounds with antioxidant effects such as vitamin C, vitamin E; HIV + patients; use of alcohol

Age
From **50 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size:

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
Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Alam -al-hoda st.
,Arak , Iran

City
Arak

Postal code

Approval date
2012-07-23, 1391/05/02

Ethics committee reference number
15-128-91

Health conditions studied

1

Description of health condition studied
drug induced hepatis

ICD-10 code
K71.1

ICD-10 code description
Toxic liver disease with hepatic necrosis

Primary outcomes

1

Description
liver enzym and if necessary bilirubin

Timepoint
start of treatment and end of first , second, third and fourth of treatment

Method of measurement
paraclinic measurement and clinical interview

Secondary outcomes

1

Description
decrease of ESR and CRP

Timepoint
start of tretment and end of first , second,third , fourth of tretment

Method of measurement
IESR and CRP measurement

Intervention groups

1

Description
in case group patients take anti TB drugs and 600 mg / BID of n-acetyl cystein for one month

Category
Prevention

2

Description
in control group patients take anti-tb drugs and 600 mg / BID of placebo for one month

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hos. and Emam reza clinic in Arak city

Full name of responsible person

Dr.aliasghar farazi

Street address

City

Aarak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical sciences

Full name of responsible person

Dr.hekmatpoo

Street address

Rresearch manager,sardasht st. ,arak,iran

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

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Full name of responsible person

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Assistant professor

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Web page address

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