

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### A comparative study of therapeutic effects of garlic and penicillamine in patients with chronic occupational lead poisoning

#### Protocol summary

##### Summary

The aim of the study is to investigate the therapeutic effects of garlic in alleviation of clinical symptoms of mild to moderate occupational lead poisoning and its effect in reducing blood lead levels. Clinical data of possible lead poisoning from more than 100 workers employed in a car battery industry will be obtained. The patients' blood and urine lead levels are measured and then workers with 200-500 µg/L lead levels who have worked for more than a year in the companies will be included in the study and randomly divided into two groups. The first group will be treated by Penicillamine 1000 mgs daily for 4 weeks and the second group will be treated by garlic 1600 mgs daily within the same period. After the one-month treatment, lead serum level will be measured and clinical and laboratory tests will be repeated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138804062083N1**

Registration date: **2010-06-19, 1389/03/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2010-06-19, 1389/03/29

##### Registrant information

##### Name

Seyed Reza Mousavi

##### Name of organization / entity

Imam Reza Hospital, Mashhad University of Medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1859 8973

##### Email address

mousavir@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2010-06-21, 1389/03/31

##### Expected recruitment end date

2010-07-22, 1389/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of therapeutic effects of garlic and penicillamine in patients with chronic occupational lead poisoning

##### Public title

A comparative study of therapeutic effects of garlic and penicillamine in patients with chronic occupational lead poisoning

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: employees who has worked more than one year in a car battery industry, blood lead levels of 200-500 µg/L Exclusion criteria: family history of allergy to penicillin and drugs that have cross-sensitivity to penicillin, antimalarial drugs and gold salt, history of agranulocytosis or anemia in previous use of penicillamine, known heart, liver or renal failure, hypersensitivity to garlic, hemorrhagic diathesis, elective surgery during and 10 days after the consumption of

garlic, using antibiotics or anticoagulant drugs

#### Age

No age limit

#### Gender

Male

#### Phase

2-3

#### Groups that have been masked

No information

#### Sample size

Target sample size: 76

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Department, Mashad University of Medical Sciences

##### Street address

2nd floor - (Central Department of Mashad University of Medical Sciences (Ghoreyshi building) - Daneshgah avenue

##### City

Mashad

##### Postal code

#### Approval date

2009-04-11, 1388/01/22

#### Ethics committee reference number

87855

## Health conditions studied

### 1

#### Description of health condition studied

Lead poisoning

#### ICD-10 code

T56.0

#### ICD-10 code description

Toxic effects of lead and its compounds

## Primary outcomes

### 1

#### Description

blood lead levels

#### Timepoint

Baseline and 1 month after the intervention

#### Method of measurement

by atomic absorption device, model Perkin Elmer 3030, through the technique of Heated Graphite Atomization

### 2

#### Description

signs and symptoms

#### Timepoint

Baseline and 1 month after the intervention

#### Method of measurement

medical examination

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

routine medical examination to find possible abnormal signs and symptoms - Complete blood count 15 days after the initiation of intervention

#### Method of measurement

Routine medical examination - Complete blood count 15 days after the initiation of treatment

### 2

#### Description

blood sugar

#### Timepoint

Baseline and 1 month after the intervention

#### Method of measurement

laboratory testing

### 3

#### Description

Lipid profile including (cholesterol, triglyceride, HDL and LDL)

#### Timepoint

Baseline and one month after the intervention

#### Method of measurement

laboratory testing

## Intervention groups

### 1

#### Description

Penicillamine Cap 250 mg 4 times daily for 4 weeks

#### Category

Treatment - Drugs

## 2

### Description

Garlic Tab 400 mg 4 times daily for 4 weeks (each tablet contains 1200 microgram allicin)

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Niroogostaran battery-making company

**Full name of responsible person****Street address****City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research Department, Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Afzal Aghayi

**Street address**

Research Department (Ghoreyshi building) - 2nd floor  
- Daneshgah Avenue

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Department, Mashhad 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**

Medical Toxicology Center

**Full name of responsible person**

Dr. Mahdi Balali Mood

**Position**

MD - Ph.D. in Clinical Pharmacology and Toxicology

**Other areas of specialty/work****Street address**

Imam Reza Hospital - Medical Toxicology Center

**City**

Mashhad

**Postal code****Phone**

+98 51 1859 8973

**Fax****Email**

mbalalimood@hotmail.com ;

balalimoodm@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Medical Toxicology Center

**Full name of responsible person**

Dr. Mahdi Balali Mood

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mbalalimood@hotmail.com ;

balalimoodm@mums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Imam Reza Hospital

**Full name of responsible person**

Sina Kianoush

**Position**

Medical student

**Other areas of specialty/work****Street address****City**

Mashhad

**Postal code****Phone****Fax****Email****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*