

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the efficacy of adding garlic to standard treatment for lead poisoning in patients referred to Razi hospital of Ahvaz

Protocol summary

Study aim

Study of the efficacy of adding garlic to standard treatment for lead poisoning

Design

This is a controlled double-blinded clinical trial. This study will be conducted on 160 individuals with lead poisoning. After coordination and obtaining informed consent, clinical examinations and blood lead concentration of all patients will be investigated. The patients (n=80 per group) will be randomly assigned into two groups of standard treatment (penicillamine) and placebo or standard treatment and garlic (4 cubes of garlic and penicillamine tablets containing the usual dose of this drug) and will be treated for 4 weeks and taking drug 3 three times daily. Lead concentration will be determined again 10 days post-treatment.

Settings and conduct

This study will be conducted on 160 individuals with lead poisoning referred to lead clinic of Razi hospital in Ahvaz. The patients will be randomly assigned into two groups of standard treatment and placebo or standard treatment and garlic and will be treated for 4 weeks. Pharmacological intervention (either garlic or placebo) and patient evaluation will be carried out by a physician who will be blinded to treatment groups. Also statistical analyzer will not know about patient grouping (double-blinded study)

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years, New lead poisoning, Consent to participate in the study; Exclusion criteria: presence of serious side effects such as the complications requiring dialysis or seizure, Failure to receive treatment for any reason.

Intervention groups

Control: standard treatment (penicillamine) and placebo. Intervention: standard treatment and garlic (4 cubes of garlic and penicillamine tablets containing the usual dose of this drug).

Main outcome variables

Reduction of Lead concentration; Symptoms of lead poisoning (hematologic and neurological symptoms); Duration of symptoms reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181104041552N1**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Seyed Manid Hosseiny

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3320 0402

Email address

hosseiny.sm@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison the efficacy of adding garlic to standard treatment for lead poisoning in patients referred to Razi hospital of Ahvaz

Public title
Efficacy garlic in treatment of lead poisoning

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years New lead poisoning Consent to participate in the study

Exclusion criteria:
Presence of serious side effects such as the complications requiring dialysis or seizure, Failure to receive treatment for any reason.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned into two groups. Assignment of patients to the study groups is done by block randomization method and using four blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
Pharmacological intervention (either garlic or placebo) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Also statistical analyzer will not know about patient grouping.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City
Ahvaz

Province
Khouzestan

Postal code
61355393

Approval date
2018-09-22, 1397/06/31

Ethics committee reference number
IR.AJUMS.REC.1397.427

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
Serum lead concentration
Timepoint
At baseline and after treatment
Method of measurement
using laboratory data (atomic absorption spectrometer)

2
Description
Symptoms of lead poisoning
Timepoint
Every week (For 4 weeks)
Method of measurement
Examination and patient history and laboratory data

Secondary outcomes

empty

Intervention groups

1
Description
Intervention group: standard treatment and garlic (4 cubes of garlic and penicillamine tablets containing the usual dose of this drug)
Category
Treatment - Drugs

2

Description

Control group: Standard treatment (penicillamine) and placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Ahmad Ghorbani

Street address

Razi Hospital, Felestin St., Amanieh

City

Ahvaz

Province

Khouzestan

Postal code

6196514941

Phone

+98 61 3333 5935

Email

Drghorbani07@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

Street address

Ahvaz Jundishapur University of Medical Sciences,
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badavim@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Abazar Parsi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Abazar Parsi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Hosseini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available