Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial comparing the impact of garlic, ginger, and placebo on serum lead levels and some hematologic and serologic factors in workers exposed to lead

Protocol summary

Study aim
To compare the impact of garlic, ginger, and placebo on serum lead levels and some hematologic and serologic factors in workers exposed to lead

Design
In this double-blind field trial, a total of 105 workers with exposure to lead (in occupations such as radiator repair, automobile body repair, soldering, etc.) will be incorporated according to inclusion criteria and via convenience sampling method. They will subsequently be allocated into one of the three groups of garlic, ginger or placebo capsules.

Settings and conduct
The study will be conducted in Birjand during 2018. In this double-blind study, the subjects studied and those measuring the outcomes will be unaware of the allocation of participants.

Participants/Inclusion and exclusion criteria
Main inclusion criteria: persons with a minimally one-year tenure in occupations that have exposure to lead; provision of informed consent to participate in study. Major exclusion criteria consist of serum lead levels lower than 5 micrograms per deciliter; serum lead levels above the therapeutic level; receiving drug to lower lead blood level during last six months; history of allergy to garlic or ginger; history of gastrointestinal ulcer, gallstones, asthma, and opiate addiction.

Intervention groups
There are three groups in this study: garlic, ginger and placebo. The garlic group will take a 400 milligram odorless garlic capsule after meal, three times a day; the ginger group will receive a 250 milligram ginger capsule after meal, three times a day; and the control group will take one placebo capsule containing cellulose after meal, three times a day. The size and color of the capsules in the placebo group are similar to those in the intervention groups. The duration of the study will be four weeks.

Main outcome variables
Blood lead level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140519017756N43**
Registration date: **2018-05-05, 1397/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-05, 1397/02/15**
Update count: **0**

Registration date
2018-05-05, 1397/02/15

Registrant information

Name
Mohammad Bagher Roozgar

Name of organization / entity
Birjand University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A clinical trial comparing the impact of garlic, ginger, and placebo on serum lead levels and some hematologic and serologic factors in workers exposed to lead

Public title
The therapeutic effects of garlic and ginger in workers exposed to lead
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Persons with a minimum of one-year tenure in occupations that have exposure to lead Informed consent to participate in study
Exclusion criteria:
Serum lead levels lower than 5 micrograms per deciliter serum lead levels above the therapeutic level Drug therapy to decrease lead blood level over the past six months History of allergy to garlic or ginger, as well as history of gastrointestinal ulcer, gallstones, asthma, and opiate addiction Being treated with aspirin and other anticoagulants or hypoglycemic agents for liver and kidney disease
Age
No age limit
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
While the study participants will be selected through convenience sampling method, they will be allocated into study group via table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The subjects studied and those measuring the outcomes will be unaware of the allocation of participants.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Ghaffari St.,
City
Birjand
Province
South Khorasan
Postal code
9717853577
Approval date
2017-01-17, 1395/10/28
Ethics committee reference number
Ir.bums.rec.1395.234

Health conditions studied

1

Description of health condition studied
lead poisoning
ICD-10 code
x49
ICD-10 code description
Accidental poisoning by and exposure to other and unspecified chemicals and noxious substances

Primary outcomes

1

Description
lead serum level
Timepoint
Before and after intervention
Method of measurement
atomic absorption device (PG Instrument Company, UK)

Secondary outcomes

1

Description
AST (Liver parameter)
Timepoint
Before and after intervention
Method of measurement
laboratory test

2

Description
Urea
Timepoint
Before and after intervention

Method of measurement
laboratory test

3

Description
Hematologic parameters
Timepoint
Before and after intervention
Method of measurement
laboratory test

4

Description
ALT (Liver parameter)
Timepoint
Before and after intervention
Method of measurement
laboratory test

5

Description
creatinine
Timepoint
Before and after intervention
Method of measurement
laboratory test

Intervention groups

1

Description
Intervention Group 1 (Garlic): For a period of four weeks, the garlic group will take three 400 milligram odorless garlic capsules after meals on a daily basis.
Category
Treatment - Other

2

Description
Intervention Group 2 (Ginger): The ginger group will receive three 250 milligram ginger capsules after meals on a daily basis for 4 weeks.
Category
Treatment - Other

3

Description
Control Group 1 (Placebo): For four weeks, the control group will have three placebo capsules containing cellulose after meals on a daily basis, where the size and color of the placebo capsules are similar to those of the intervention groups.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nursing Research Center
Full name of responsible person
Marzieh Mogharab
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Sareh Nakhaei
Position
MSc Student of Nursing
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
Deidentified Individual Participant Data Set (IPD)
When the data will become available and for how long
The file will be available after the extracted paper is published for as long as 6 months from the publication of the paper.
To whom data/document is available
to those who request for it
Under which criteria data/document could be used
for research purposes only
From where data/document is obtainable
personal email to authors
What processes are involved for a request to access data/document
personal correspondence via email
Comments