

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation the effect of Silymarin on reducing lead blood concentration and oxidative stress biomarkers in opioid addicts.

Protocol summary

Study aim

Effect of Silymarin Supplement on Reducing Blood lead level and Oxidative Stress Biomarkers in opium addicted People

Design

This is an interventional study and 60 drug addicts referred to Addiction Treatment Center of Farshchan Sina Hospital will be conducted within three months. Patients referred to the center after the initial visit and admission to the study are randomly assigned to one of the two following groups: receiving the drug or receiving the placebo.

Settings and conduct

Patients referred to the center after the initial visit and admission to the study are randomly assigned to one of the two following groups: receiving the drug or receiving the placebo. The Silymarin group will include people who receive 420 mg (140 mg three times a day) of silymarin seven days a week for three months each day, and the control group (placebo group) will include people who are taking the same dose as Silymarin, which is a substance Does not have any effect. Acceptance of patients will be done through the counting of pills, as well as the daily records that will be provided to them. A daily logbook of drug intake will be sent to the control center every month, and will receive a monthly allowance for their pills.

Participants/Inclusion and exclusion criteria

People enrolled in the study will have the following conditions: • The age group is 18 to 60 years old • Serum lead levels greater than 10mcg / dl • History of opium use

Intervention groups

Patients referred to the center after the initial visit and admission to the study are randomly assigned to one of the two following groups: receiving the drug or receiving the placebo. The Silymarin group will include people who receive 420 mg (140 mg three times a day) of silymarin seven days a week for three months each day, and the

control group (placebo group) will include people who are taking the same dose as Silymarin, which is a substance Does not have any effect. Acceptance of patients will be done through the counting of pills, as well as the daily records that will be provided to them. A daily logbook of drug intake will be sent to the control center every month, and will receive a monthly allowance for their pills.

Main outcome variables

blood lead level lipid peroxidation levels of serum thiol (protein oxidation) DNA damage (8-hydroxy-deoxy-guanosine)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037584N1**

Registration date: **2018-01-07, 1396/10/17**

Registration timing: **prospective**

Last update: **2018-01-07, 1396/10/17**

Update count: **0**

Registration date

2018-01-07, 1396/10/17

Registrant information

Name

Mojdeh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1593

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of Silymarin on reducing lead blood concentration and oxidative stress biomarkers in opioid addicts.

Public title

Investigation the effect of herbal supplement on lead concentration

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18-60 years old blood lead level>10mcg/dl opium abuser

Exclusion criteria:

Age under 18 years Get other types of other antioxidants
Gastrointestinal diseases, especially absorption disorders, which can affect the effective absorption of the drug
History of heart, kidney, and liver disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization In this study, a simple random lottery method will be used. In this method all units or individuals listed or their names are provided. And then they will be divided into two groups by lot.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are blind (placebo or treatment)

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan university of medical sciences, Shaheed Fahmideh Blvd, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2017-11-04, 1396/08/13

Ethics committee reference number

IR.UMSHA.REC.1396.555

Health conditions studied**1****Description of health condition studied**

lead poisoning

ICD-10 code

R78.71

ICD-10 code description

Abnormal lead level in blood

Primary outcomes**1****Description**

Blood lead level

Timepoint

Blood lead level measurement before drug interventions and And three months after use of the medication.

Method of measurement

Atomic absorption

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this study, the intervention group included the active ingredient of silymarin in the form of a Livergol produced by Gol-Daru Company receives 420 mg daily (three times every 140 mg) for three months.

Category

Treatment - Drugs

2

Description

Control group: A group that receives a pill similar to Livergel as a placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction Treatment Center at Farshchan educational and medical center

Full name of responsible person

Dr. Saeed Afzali

Street address

Mirzadeh Eshqi St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mojdeh Mohammadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The whole data of individuals unidentifiably

When the data will become available and for how long

After publication the article, results will be available

To whom data/document is available

Data is available to the public after being publicized.

Under which criteria data/document could be used

For further studies

From where data/document is obtainable

m.mohammadi@umsha.ac.ir

What processes are involved for a request to access data/document

Sending email is enough

Comments