Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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
City
Hamadan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3827 4191
Email
m.mohammadi@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
Hamadan unirsity of medical sciences, Shaheed Fahmideh Blvd
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m.mohammadi@umsha.ac.ir
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
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Other areas of specialty/work
Toxicology
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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
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 unidentifiablely
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